QUALITY MANUAL

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Table of Contents

Table of Tables

Table of Figures

Section 3

INTRODUCTION AND SCOPE
(TNI V1:M2 – Sections 1, 2, 3)

The purpose of this *Quality Manual* is to outline the quality management system for PDC Laboratories, Inc. The *Quality Manual* defines the policies, procedures, and documentation that assure analytical services continually meet a defined standard of quality that is designed to provide clients with data of known and documented quality and, where applicable, demonstrate regulatory compliance.

The *Quality Manual* sets the standard under which all laboratory operations are performed, including the laboratory's organization, objectives, and operating philosophy. The *Quality Manual* has been prepared to assure compliance with the 2009 TNI Environmental Laboratory Sector Standard – Volume 1 **–** Management and Technical Requirements for Laboratories Performing Environmental Analysis (EL-V1-M1 through M7-ISO-2009). This Standard is consistent with ISO/IEC 17025:2005 requirements that are relevant to the scope of environmental testing services and thus, the laboratory operates a quality system in conformance with ISO/IEC 17025:2005(E). In addition, the policies and procedures outlined are compliant with the various accreditation and certification programs listed in Appendix E.

In addition, the *Quality Manual* has been prepared to be consistent with the requirements of the following documents:

1. Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition,
2. Standard Methods for the Examination of Water and Wastewater, as updated by MUR II,
3. 40 CFR Part 136 including Appendices,
4. Test Methods for Evaluating Solid Waste: SW-846,
5. State–specific analytical methods (such as OA-1 and OA-2 for State of Iowa), and
6. Title 77 Illinois Administrative Code, Chapter I, Subchapter d, Part 465 – Certification and Operation of Environmental Laboratories (Microbiology)

3.1 Scope of Testing

The laboratory's scope of analytical testing services includes those listed in Appendix E. Copies of current certificates and parameter lists for each organization are available upon request from the Quality Assurance Department.

3.2 Table of Contents, References and Appendices

The Table of Contents is in Section 2 and Appendices follow Section 28.

This *Quality Manual* uses the references included in Modules 1-7 in the 2009 TNI Environmental Laboratory Sector Standard – Volume 1 – Management and Technical Requirements for Laboratories Performing Environmental Analysis.

3.3 Glossary and Acronyms Used

Quality control terms are generally defined within the Section that describes the activity.

3.3.1 Glossary

A consolidated list of terms and definitions is found in Appendix D.

3.3.1.1 **The TNI Standard:** Terms and definitions may also be found in Modules 1-7 in the 2009 TNI Environmental Laboratory Sector Standard – Volume 1 – Management and Technical Requirements for Laboratories Performing Environmental Analysis (EL-V1, M1 through M7, ISO-2009).

3.3.2 Acronyms

A list of acronyms used in this document and their definitions are found at the end of Appendix D.

3.4 Management of the *Quality Manual*

The Director of Quality Assurance is responsible for maintaining the currency of the *Quality Manual*.

The *Quality Manual* is reviewed every two (2) years by the Director of Quality Assurance and laboratory personnel to ensure it still reflects current practices and meets the requirements of any applicable regulations or client specifications. Sections of the manual are updated by making a change to the Section and then increasing the revision number by one. The cover sheet of the *Quality Manual* (Section 1) must be re-signed and the Table of Contents (Section 2) is updated whenever a Section is updated.

The *Quality Manual* is considered confidential within PDC Laboratories, Inc. and may not be altered in any way except by approval of the Laboratory Vice President and Director of Quality Assurance. If it is distributed to external users, it is for the purpose of reviewing PDC Laboratories, Inc.'s quality management system and may not be used for any other purpose without written permission. Hardcopy printed versions of the *Quality Manual* are not considered controlled documents.

Section 4

ORGANIZATION
(TNI V1:M2 – Section 4.1)

The laboratory is a legally identifiable organization. The laboratory is responsible for carrying out testing activities that meet the requirements of the TNI Standard, the ISO/EIC 17025 Standard, and that meet the needs of the client. Through application of the policies and procedures outlined in this Section and throughout the *Quality Manual*:

- The laboratory assures that it is impartial and that personnel are free from undue commercial, financial, or other undue pressures that might influence their technical judgment.
- Management and technical personnel have the authority and resources to carry out their duties and have procedures to identify and correct departures from the laboratory's management system.
- Personnel understand the relevance and importance of their duties as related to the maintenance of the laboratory's management system.
- Ethics and data integrity procedures (see Appendix A, Section 5 – "Management" and Section 19 – "Data Integrity Investigations") ensure personnel do not engage in activities that diminish confidence in the laboratory's capabilities.
- Confidentiality is maintained.

4.1 Organization

PDC Laboratories, Inc., incorporated in the State of Illinois in 1981, is a commercial environmental and analytical laboratory group serving diverse clients in the industrial, government, engineering, consulting and private sectors. Documentation of legal identification is available upon request.

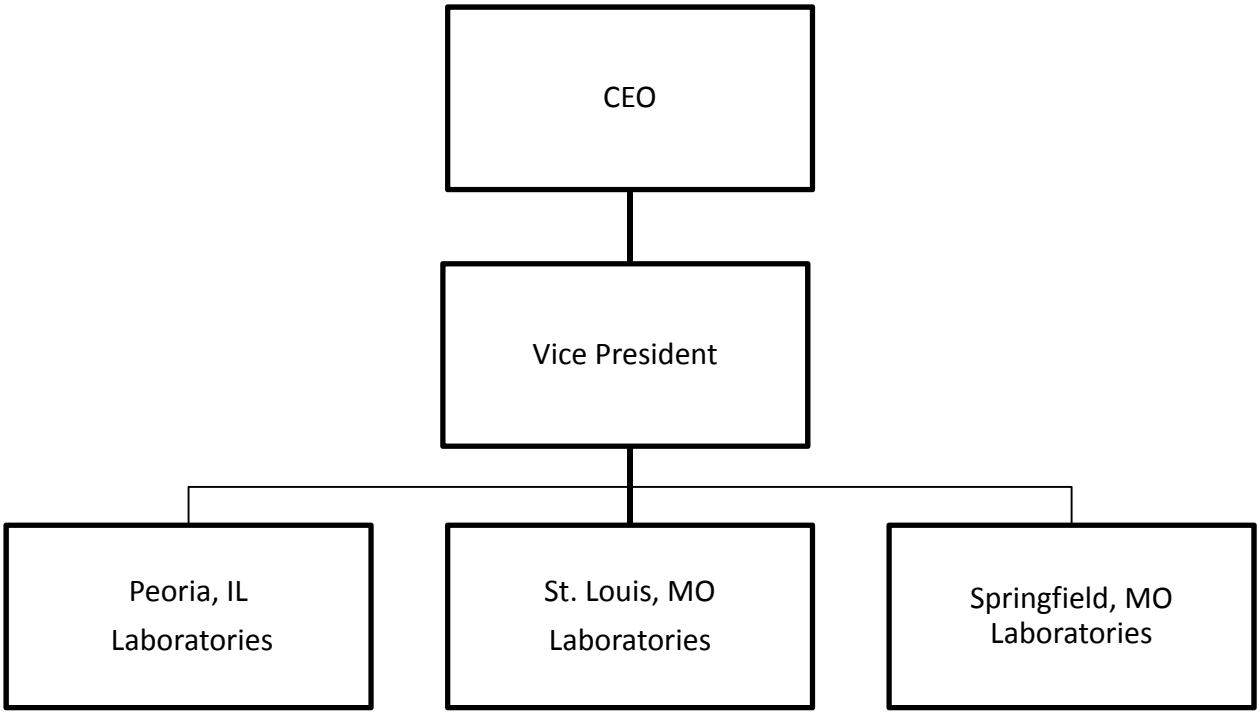
Laboratories at three locations comprise the laboratories group – Peoria, Illinois, Florissant, Missouri (St. Louis, MO area), and Springfield, Missouri. PDC Laboratories, Inc. is a wholly owned subsidiary of Coulter Companies, Inc.

A general corporate organization chart can be found in Figure 4-1.

The laboratory's organization chart can be found in Appendix B. Additional information regarding responsibilities, authority and interrelationship of personnel who manage, perform or verify testing is included in Section 5 –"Management" and Section 20 – "Personnel". These Sections also include information on supervision, training, technical management, job descriptions, quality personnel, and appointment of deputies for key managerial personnel.

The laboratory has the resources and authority to operate a management system that is capable of identifying departures from that system and from procedures during testing, and initiates actions to minimize or prevent departures.

Figure 4-1 – Corporate Organization Chart



4.2 Conflict of Interest and Undue Pressure

The organizational structure indicated in Appendix B minimizes the potential for conflicting or undue interests that might influence the technical judgment of analytical personnel. In addition, procedures are in place to prevent outside pressures or involvement in activities that may affect competence, impartiality, judgment, operational integrity, or the quality of the work performed at the laboratory.

A conflict of interest can occur when outside activities or personal interests interfere or appear to interfere with the ability to objectively perform the work assignment or act in the best interest of PDC Laboratories, Inc. Employees have an obligation to avoid actual or potential conflicts of interest. Employees are to contact the Corporate Human Resources Department for more information or questions about conflicts of interest.

Business dealings with outside firms should not result in unusual gains for those firms. Unusual gain refers to bribes, product bonuses, special fringe benefits,

unusual price breaks, and other windfalls designed to ultimately benefit the employer, the employee, or both.

An actual or potential conflict of interest occurs when an employee is in a position to influence a decision that may result in a personal gain for that employee or for a relative as a result of the laboratories' business dealings. For the purposes of this policy, a relative is any person who is related by blood or marriage, or whose relationship with the employee is similar to that of persons who are related by blood or marriage.

If an employee has any influence on transactions involving purchases, contracts, or leases, it is imperative that the employee disclose to the Corporate Human Resources Department or the Laboratory Vice President, as soon as possible, the existence of any actual or potential conflict of interest so that safeguards can be established and/or other appropriate decisions can be made to protect all parties. The Laboratory Vice President must contact the CEO in regards to their situations of potential conflict of interest.

Personal gain may result not only in cases where an employee or relative has a significant ownership in a firm with which the laboratories do business, but also when an employee or relative receives any kickback, bribe, substantial gift, or special consideration as a result of any transaction or business dealings involving the laboratory.

Situations which create the appearance of a conflict should be avoided as well.

All financial, business and other activities both inside and outside of the job must be lawful and free of conflicts or even the suggestion of a conflict with responsibilities as a PDC Laboratories, Inc. employee.

Section 5

MANAGEMENT
(TNI V1:M2 – Section 4.2)

The laboratory maintains a management system that is appropriate to the scope of its activities.

5.1 Management Requirements

Corporate Management includes the Chief Executive Officer (CEO), Chief Financial Officer (CFO), Vice Presidents, Directors, Managers, and Supervisors. The CEO establishes the overall management system and data integrity program for the company, providing the necessary leadership and resources to assure that the management system and integrity program requirements are met.

Senior Management at PDC Laboratories, Inc. includes the Laboratory Vice President, Director of Quality Assurance, Director of Sample Logistics, Corporate Information Technology Manager, Senior Project Manager, and Facility Manager. The Laboratory Department Managers, Laboratory Supervisors and Project Managers may be included if the need arises.

Management's commitment to good professional practice and to the quality of its products is defined in the Quality Policy statement, Section 5.3

Management has overall responsibility for the technical operations and the authority needed to generate the required quality of laboratory operations. Management ensures communication within the organization to maintain an effective management system and to communicate the importance of meeting client, statutory, and regulatory requirements. Management assures that the system documentation is known and available so that appropriate personnel can implement their part of the management system. When changes to the management system occur or are planned, managers ensure that the integrity of the system is maintained.

Management is responsible for carrying out testing activities that meet the requirements of the TNI Standard, the ISO/IEC 17025 Standard, and that meet the needs of the client.

Managers implement, maintain and improve the management system, and identify noncompliance with the management system of procedures. Managers initiate actions to prevent or minimize noncompliance.

Management ensures technical competence of personnel operating equipment, performing tests, evaluating results, or signing reports, and limits authority to perform laboratory functions to those appropriately trained and/or supervised as documented by training records.

Management is responsible for defining the minimal level of education, qualifications, experience, and skills necessary for all positions in the laboratory and assuring that technical staff have demonstrated capabilities in their tasks.

Training is kept up to date as described in Section 20 – "Personnel" by periodic review of training records and through employee performance reviews.

Management bears specific responsibility for maintenance of the management system. This includes defining roles and responsibilities to personnel, approving documents, providing required training, providing a procedure for confidential reporting of data integrity issues, and periodically reviewing data, procedures, and documentation. The assignment of responsibilities, authorities, and interrelationships of the personnel who manage, perform, or verify work affecting the quality of environmental tests is documented in the organizational chart found in Appendix B and in Section 20 of this manual

Management ensures that audit findings and corrective actions are completed within required time frames.

If the Vice President, a Director or a Department Manager is absent for fifteen (15) consecutive calendar days or more, a deputy with appropriate qualifications will perform the Vice President's, Director's or Department Manager's duties. Beyond a thirty-five (35) consecutive calendar day absence, management will notify the primary accreditation body in writing of the absence of the Vice President, Director or Department Manager and the appointment of a deputy.

5.2 Management Roles and Responsibilities

5.2.1 Laboratory Vice President

The Laboratory Vice President is responsible for the overall quality, safety, financial, technical, human resource and service performance of the laboratory. The Laboratory Vice President provides the resources necessary to implement and maintain an effective quality and data integrity program. Signatory approval is unrestricted as a corporate officer.

The Laboratory Vice-President's training and proof of experience and education are available in training records maintained by the Quality Assurance Department.

5.2.1.1 Responsibilities

The Laboratory Vice President is responsible for:

a. ensuring that personnel are free from any commercial, financial and other undue pressures that might adversely affect the quality of their work;

b. ensuring that all analysts and supervisors/managers have the appropriate education and training to properly carry out the duties assigned to them and ensures that this training has been documented;

c. ensuring that the annual management review meeting is held and used as a forum for discussions concerning: the suitability of policies and procedures, reports from managerial and supervisory personnel, the outcomes of recent internal audits with related possible corrective actions and potential preventive actions, assessments by external bodies, results of proficiency testing, changes in volume and type of work, client feedback, complaints, recommendations for improvements, and other relevant items such as quality control activities, use of resources and staff training;

d. ensuring that appropriate corrective actions are taken to address analyses identified as requiring such actions by internal and external performance or procedural audits; (Procedures that do not meet the standards set forth in the Quality Manual, laboratory SOPs or laboratory policies may be temporarily suspended by the Laboratory Vice President.)

e. ensuring that all SOPs and policies have been reviewed and approved prior to their implementation and ensures all approved SOPs and policies are provided to laboratory personnel and are adhered to;

f. facilitating a two-way exchange of information between the laboratory and corporate management as the intermediary between the laboratory and corporate office;

g. general and financial planning, revenue budgeting, expense budgeting, and capital budgeting; and

h. determining the availability of the laboratory to accept new projects. This availability includes considerations of equipment, facilities, staff, experience, etc.

5.2.2 Director of Quality Assurance

The Director of Quality Assurance is responsible for all quality assurance (QA) and quality control (QC) activities and is independent from laboratory operations. The Director of Quality Assurance's training and proof of experience in QA/QC procedures, knowledge of analytical methods, and the laboratory's management system are available in training records maintained by the Quality Assurance Department.

5.2.2.1 Responsibilities

The Director of Quality Assurance is responsible for:

a. serving as a focal point for QA/QC;

b. direction and training of the quality assurance staff;

c. planning and budgeting for the QA Department;

d. ensuring that Standard Operating Procedures (SOPs) are maintained, updated as needed, and followed;

e. arranging or conducting annual internal audits without outside (e.g., managerial) influence;

f. oversight of analysis and reporting of Performance Testing (PT) samples;

g. notifying management of deficiencies, and monitoring corrective actions;

h. oversight and review of quality control data;

i. ensuring that the management system related to quality is implemented and followed at all times;

j. arranging external audits;

k. maintaining a base of approved subcontract laboratories (with the assistance of the Director of Sample Logistics);

l. assisting with and/or advising on laboratory procedure development and implementation;

m. monitoring and maintaining laboratory certifications; and

n. ensuring that this *Quality Manual* is kept current.

5.2.3 Director of Sample Logistics

The Director of Sample Logistics is responsible for budgeting, departmental purchasing, departmental training and the day-to-day performance of the shipping, receiving and courier staff members.

The responsibilities of these sections are to send approved sample containers to clients, pick up samples if required, receive, unpack and inspect samples after delivery, log the samples into the LIMS and maintain the organization and storage of samples housed during analysis.

The Director of Sample Logistics' training and proof of experience and education are available in training records maintained by the Quality Assurance Department.

5.2.3.1 Responsibilities

The Director of Sample Logistics is responsible for:

a. evaluation and ordering approved sample containers;

b. sending samples to subcontracted laboratories for non-routine or overflow analyses;

c. coordinating and controlling the order cycle and associated storage and movement of sample containers between storage and clients;

d. using maps, discussions with couriers, and the Internet to determine best routes to use for container delivery and sample pick-up;

e. analyzing data to monitor performance and plan improvements in delivery performance;

f. oversight of vehicle acquisition and vehicle repair;

g. coordinating with all required freight carriers including negotiating prices and conditions regularly;

h. coordinating, monitoring, and reporting internal bottle QC; and

i. maintaining daily sample receipt report as an electronic file.

5.2.4 Information Technology Manager

The Information Technology Manager, a Corporate employee, is responsible for management of electronic records, electronic data archival storage, operational integrity of the electronic data systems, research and development of automated laboratory information management procedures, budgeting and staff training related to the use of the LIMS.

5.2.4.1 Responsibilities

The Information Technology Manager is responsible for:

a. devising the overall IT framework comprised of all the IT procedures, practices, procurement and setting up and maintenance of the IT infrastructure encompassing internet resources, network resources, electronic communications infrastructure, and information technologies infrastructure;

b. leading an internal IT team who is responsible for managing and maintaining day-to–day operations of the IT infrastructure with delegation of day-to-day responsibilities of PDC Laboratories, Inc. to the Laboratory System Administrator;

c. dealing with external IT vendors, suppliers and outsourcing partners and software developers to buy IT assets;

d. ensuring that new IT hires are trained with completed training documentation submitted to the Quality Assurance Department;

e. delivering IT and IT allied services to the organization; and

f. ensuring that the PDC Laboratories, Inc. staff is trained in the laboratory Electronic Communications Policy. Required documentation of training is maintained by the Quality Assurance Department.

5.2.5 Senior Project Manager

The Senior Project Manager is responsible for oversight of various client services such as primary and secondary project management duties as well as back-up to other project managers. The Senior Project Manager is a liaison with the marketing staff and a link between the laboratory department managers and other project managers.

The Senior Project Manager's training and proof of experience and education are available in training records maintained by the Quality Assurance Department

5.2.5.1 Responsibilities

The Senior Project Manager is responsible for:

a. implementing quality assurance procedures and review in accordance with the laboratory methodology and procedures to ensure successful execution of the project as measured by clients' data quality objectives (DQOs);

b. setting appropriate and correct pricing and ensuring accurate invoicing;

c. documenting complaints received from clients so that the Quality Assurance Department can track and monitor the complaint process;

d. documenting instances of "Service to the Client" so that the Quality Assurance Department can verify compliance with the TNI Standard;

e. working in conjunction with sales team to follow up on sales;

f. growing long-term relationships with clients;

g. effectively communicating relevant project information to laboratory personnel;

h. raising laboratory visibility through involvement in local industry organizations;

i. possessing a thorough understanding of laboratory offerings, technical preferences, and technical direction;

j. continually seeking and capitalizing upon opportunities to increase client satisfaction and deepen client relationships;

k. anticipating client needs and proposing alternative business solutions;

l. identifying partnership opportunities and capitalizes on “add-on” sales opportunities across projects; and

m. possessing a knowledge base of each client’s business, organization and objectives.

5.2.6 Project Managers

The project managers are responsible for assisting clients in the administration of their sampling and analysis programs. Projects are assessed and assigned to specific project managers based on the general nature of the work. Typically, projects are categorized as municipal wastewater, municipal drinking water, industrial waste, industrial wastewater, groundwater, clean-up and remediation, homeowner (“private clients”) or as samples in accordance with Federal contracted program-specific requirements.

The Project Manager’s training and proof of experience and education are available in training records maintained by the Quality Assurance Department

5.2.6.1 Responsibilities

The Project Managers are responsible for:

a. informing clients of the PDC Laboratories, Inc. Sample Acceptance Policy;

b. obtaining project specific requirements regarding data quality objectives (DQOs) or regulatory requirements, turn-a-round times, number of samples, matrix, analytes, methods, reporting limits, required quality control elements, evidentiary requirements, and report requirements (QC summary forms, CLP-like forms, case narratives, etc.);

c. effectively communicating relevant project information to laboratory personnel;

d. obtaining a current copy of the client’s Quality Assurance Project Plan, if required;

e. setting up the account information in the LIMs (create clients, bids, and projects);

f. setting up analyses or custom analyses as needed for login;

g. arranging for the delivery and receipt of sample containers;

h. informing applicable laboratory personnel of non-routine/special requests or expedited analysis requirements;

i. oversight of sample login and review of submitted documentation;

j. monitoring sample progress through the laboratory;

k. report generation;

l. answering project inquiries by the client;

m. documenting complaints received from clients so that the Quality Assurance Department can track and monitor the complaint process;

n. documenting instances of "Service to the Client" so that the Quality Assurance Department can verify compliance with the TNI Standard;

o. reporting any potential problems to the client in a timely fashion; and

p. generation and review of invoices for work performed.

5.2.7 Facility Manager

The Facility Manager is responsible for oversight of facility and grounds maintenance, evaluates use of space and facilities, supervisor of facility support personnel, facility security, management of hardcopy records, archival hardcopy storage and hardcopy data destruction.

The Facility Manager and designee are also on call and have to be available during non-working hours in case of emergencies.

The Facility Manager's training and proof of experience are available in training records maintained by the Quality Assurance Department

5.2.7.1 Responsibilities

The Facility Manager is responsible for:

a. ensuring the laboratory facility operates as efficiently as possible;

b. improving the facility's energy efficiency to meet government environmental regulations;

c. overseeing and directing maintenance personnel and workers engaged in equipment installation, facilities equipment repair and preventative maintenance.

d. oversight of the sampling and reporting of wastewater effluent monitoring to comply with the Greater Peoria Sanitary District (GPSD) permit requirements

e. maintaining a Class K Operator's permit in order to maintain the on-site Pretreatment Works;

f. maintaining the recycling program;

g. coordinating with the Director of Quality Assurance in developing and running the ethics training program;

h. performing new employee orientation; and

i. participating in both hazardous and non-hazardous waste storage and disposal procedures including auditing and documentation of storage, assisting in transferring containers of waste from the facility to the hazardous waste storage location and disposal. Duties do not include handling or labeling any of the designated hazardous waste streams

5.2.8 Department Managers (Organic/Metals/Inorganic/Microbiology/Field)

The Department Manager (or designee) is a full-time laboratory staff member who supervises laboratory operations and data reporting. The Department Manager meets the education and qualification requirements of Section 5.2.6.1 of the TNI Standard – EL–V1M2-2009 by possessing at least a bachelor's degree in the chemical, environmental, biological or physical sciences or engineering with at least two years of experience in the environmental analysis of representative inorganic or organic analytes for which the laboratory seeks or maintains accreditation**.**

The Department Manager's proof of experience in the fields of accreditation may be found in training records maintained by the Quality Assurance Department

The Department Manager is not a department manager of more than one accredited environmental laboratory.

5.2.8.1 Responsibilities

The Department Manager is responsible for:

a. exercising actual-day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results;

b. monitoring standards of performance data in quality control and quality assurance;

c. monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data;

d. planning and budgeting;

e. active in the hiring of new staff and ensuring that personnel have the appropriate education and technical background to perform the tests for which the laboratory is accredited;

f. providing necessary training as needed; and

g. leading laboratory procedure development and implementation.

5.2.9 Laboratory Key Personnel Deputies

Key Personnel Deputies with appropriate qualifications are appointed as needed.

5.3 Quality Policy

Management's commitment to quality and to the management system is stated in the Quality Policy below, which is upheld through the application of related policies and procedures described in the laboratory's *Quality Manual*, SOPs and policies.

Quality Policy Statement

The mission of PDC Laboratories, Inc. is to generate and report data of known and documented quality in a fashion that meets our clients' requirements. Our policy is to use good professional practices, to maintain quality, to uphold the highest quality of service and to comply with the TNI Standard. In support of this mission, our quality assurance program has been implemented as an integral part of laboratory management and practice. The PDC Laboratories, Inc. Quality Manual (QM) describes the standard practices and requirements that have been established to assure the quality of the laboratories' services. It describes the requirements, implementation, management and review of these practices. The Laboratory Vice President, directors, department managers, section supervisors and staff members are individually obligated to comply with its stated requirements, responsibilities and objectives.

The PDC Laboratories, Inc. management is committed to comply with the TNI Standard and will continually improve the effectiveness of the management system that results from implementation of the Standard in its entirety. Each staff member must familiarize themselves with the quality documentation and to implement the quality policies and procedures in their work. Every laboratory employee must ensure that the generation and reporting of quality analytical data is a fundamental priority.

The laboratory ensures that personnel are free from any commercial, financial, and other undue pressures, which might adversely affect the quality of work. All employees are trained annually on ethical principles and procedures surrounding the data that is generated. The laboratory maintains a strict policy of client confidentiality.

Updates and modifications to the QM will be made as needed. The Quality Assurance Department has the authority to make these changes as well as the responsibility of verifying the adherence to technical policies and procedures. All revisions to the QM are reviewed and authorized by laboratory management prior to their release and implementation.

5.4 Ethics and Data Integrity System

The laboratory has an Ethics and Data Integrity policy that is included in Appendix A. The laboratory's Ethics and Data Integrity program, training and investigations are discussed in Section 19 – "Data Integrity Investigations".

5.5 Documentation of Management/Quality System

The management system is defined through the policies and procedures provided in this *Quality Manual* and written laboratory Standard Operating Procedures (SOPs) and documented policies.

5.5.1 Quality Manual

The *Quality Manual* contains the following required items:

5.5.1.1 document title;

5.5.1.2 laboratory's full name and address;

5.5.1.3 name, address (if different from above), and telephone number of individual(s) responsible for the laboratory;

5.5.1.4 identification of all major organizational units which are to be covered by this quality manual and the effective date of the version;

5.5.1.5 identification of the laboratory's approved signatories;

5.5.1.6 the signed and dated concurrence (with appropriate names and titles), of all responsible parties including the agent who is in charge of all laboratory activities – the Laboratory Vice President and the Director of Quality Assurance.

5.5.1.7 the objectives of the management system and contain or reference the laboratory's policies and procedures;

5.5.1.8 the laboratory's official quality policy statement, which shall include management system objectives and management's commitment to ethical laboratory practices and to upholding the requirements of this Standard; and

5.5.1.9 a table of contents, and applicable lists of references, glossaries and appendices.

This *Quality Manual* contains or references all required elements as defined by the TNI Standard - V1:M2, Section 4.2.8.4.

5.5.2 Standard Operating Procedures (SOPs)

Standard Operating Procedures (SOPs) represent all phases of current laboratory operations (they include a date, revision number, and signature of the approving authorities) and are available to all personnel. They contain sufficient detail such that someone with similar qualifications could perform the procedures. The SOP entitled Standard Operating Procedures describes the preparation and use of SOPs within the laboratory quality system. There are two types of SOPs used in the laboratory: 1) test method SOPs, which have specific requirements as outlined below, and 2) general use SOPs which document general, non-analytical procedures.

Each accredited analyte or method has an SOP. The laboratory's test method SOPs include the following topics, where applicable:

1. Scope and Application – describe the purpose of the process or procedure

2. Summary – briefly summarizes the procedure

3. Definitions – identify any specialized terms used

4. Interferences – describe any component of the process that may interfere with the accuracy of the final product

5. Safety – general safety issues

6. Equipment & Supplies – listing of applicable equipment and materials, including instrumentation and pertinent software applications

7. Reagents & Standards – list of reagents and chemical standards

8. Sample, Collection, Preservation, Holding Times - list of collection bottles, temperature and preservation additives and method applicable holding times)

9. Quality Control/Corrective Action and Contingencies for Out-of-Control Data – required QC with corrective actions when applicable

10. Calibration – instrument or method calibration or standardization

11. Procedure/Instrument Analysis – such as extraction, digestion, analysis, identification

12. Additional Corrective Action and Contingencies for Out-of-Control Data – list corrective action for samples and method specific occurrences

13. Calculations – list any mathematical steps to be followed

14. Method Performance – MDL information

15. Pollution Prevention – disposal of samples

16. Waste Management – disposal of laboratory waste

17. References – any procedures that interface with the SOP such as methods, including revision or published literature

18. Tables, Diagrams, Flow Charts & Validation Data – any related attachments

19. Revision Record – traceability of revision changes

20. Addendums – additional information as needed

Each general use SOP includes the Cover page – Signatory Section (must include approval signatures with date) and the following sections:

1. Purpose

2. Scope

3. Procedure

4. Tables/Attachments

5. Revision Record

6. Addendum (as needed)

7. References(as needed)

5.5.3 Order of Precedence

In the event of a conflict or discrepancy between policies, the order of precedence is as follows unless otherwise noted:

- Quality Manual (unless a specific SOP is referenced in manual)
- SOPs
- Documented Policies
- Other (Work Instructions, memos, flow charts, etc.)

Section 6

DOCUMENT CONTROL
(TNI V1:M2 – Section 4.3)

This Section describes how the laboratory establishes and maintains a process for document management. Procedures for document management include controlling, distributing, reviewing, and accepting modifications. The purpose of document management is to preclude the use of invalid and/or obsolete documents.

Documents can be SOPs, documented procedures, policy statements, specifications, calibration tables, charts, textbooks, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

The laboratory manages three types of documents: 1) controlled, 2) approved, and 3) obsolete.

A controlled document is one that is uniquely identified, issued, tracked, and kept current as part of the management system. Controlled documents may be internal or external documents. An example of a controlled document is a standard operating procedure (SOP).

An approved document means it has been reviewed and either signed and dated, or acknowledged in writing or by secure electronic means by the issuing authority (ies).

Obsolete documents are documents that have been superseded by more recent versions or are no longer needed and have been archived.

6.1 Controlled Documents

Documents will be reviewed, revised (as appropriate) and approved for use by the appropriate level of management for that type of document prior to issue.

Documents are reviewed every two to three years depending on the type of document or as needed to ensure their contents are suitable and in compliance with the current management systems requirements, and accurately describe current operations.

Approved copies of documents are available to staff at all locations where operations are essential to the effective functions of the laboratory. For example, all technical SOPs are available electronically - analysts are able to view the SOPs on computers at work stations. These documents are in PDF format and are generally maintained on a network that all computers have access to. However, aside from the QA Department, copying or printing of SOPs is forbidden. Hardcopy versions must be requested from the QA Department. Prior to performing a procedure for the first time, the individual must document in writing that they have “Read and Understood” the specific SOP.

Controlled internal documents are uniquely identified with 1) a unique name and number identification 2) date of issue, 3) revision identification, 4) page number, 5) the total number of pages, and 6) the signatures of the issuing authority (i.e. management)

A master list of controlled internal documents such as SOPs is maintained that includes description, number, revision, date and means of distribution. The controlled document list is maintained by the QA Department and is updated as needed.

6.1.1 Document Changes to Controlled Documents (SOPs)

6.1.1.1 Paper Document Changes

If it is found that a given procedure is not performed in accordance with the current SOP or does not accurately describe the procedure or equipment used, the SOP must be revised immediately. Prior to any change to the SOP, the original signatories and the QA Department must be advised of the change and approve the change. The department manager must determine the effect, if any, the deviation may have on the integrity of data.

Document changes are approved by the original approving authority and the QA Department.

A SOP modification form must be completed before any changes can be implemented. Handwritten modifications are not allowed.

All document modifications are approved. Changes that are not process modifications but clarifications may be performed without revision. Approval is required. The modified document is then copied and distributed, and obsolete documents are removed according to the master list of controlled documents.

Amendments/modifications to documents are incorporated into a new revision and reissued when the document is reviewed and updated on or before its scheduled review cycle.

A reason for the modification or change is provided as historical information in the revised document.

6.1.1.2 Electronic Document Changes

The same process that occurs with paper document changes is followed with electronic document changes.

Suggested revisions to electronic documents are presented to the QA Department for review and approval. Changes to electronic documents are approved either on a change or modification form or through electronic means such as email or system messages. Where practical, the altered text

or new text in the draft is identified during the revision or review process to provide for easy identification of the modifications.

6.2 Obsolete Documents

All invalid or obsolete documents are removed from general distribution, or otherwise prevented from unintended use.

Obsolete paper documents are collected from employees when a new revision is released. The master copy with original signatures is retained for legal use or historical knowledge preservation. The front page is marked “VOID” and retained by the QA Department. Electronic versions of the documents are archived on the laboratory server under the QA Department.

Section 7

REVIEW OF REQUESTS, TENDERS AND CONTRACTS
(TNI V1:M2 – Section 4.4)

The review of all new work assures that oversight is provided so that requirements are clearly defined, the laboratory has adequate resources and capability, and the test method is applicable to the client's needs. This process assures that all work will be given adequate attention without shortcuts that may compromise data quality.

Contracts for new work may be formal bids, signed documents, verbal, or electronic. The client's requirements, including the methods to be used, must be clearly defined, documented and understood. Requirements might include target analyte lists, project specific reporting limits (if any), project specific quality control requirements (if any), turnaround time, and requirements for data deliverables. The review must also cover any work that will be subcontracted by the laboratory.

7.1 Procedure for the Review of Work Requests

Projects are assessed and assigned to specific project managers based on the nature of the work. Typically, projects are categorized by market segments such as municipal drinking water, groundwater, municipal wastewater, industrial wastewater, industrial waste, clean-up/remediation, homeowner ("private clients") or Federal/State programs. The project manager responsible for that market segment is allowed to use discretion in accepting work that is of a routine or on-going nature for PDC Laboratories, Inc. after confirming that the laboratory has any required certifications, that it can meet the client's data quality and reporting requirements and that the laboratory has the capacity to meet the client's turn-around needs.

Any new, large or complex (non-routine) projects that have the potential to impact the normal workflow of the laboratory are cleared by the appropriate Department Manager and/or the Laboratory Vice President.

The work request review process can vary even with the same client ranging from a simple verbal request with approval to a formal request for bid or proposal with negotiation. These requests can also involve formal contracts covering aspects such as insurance requirements, payments terms and other work-specific conditions.

Based on the results of the initial inquiry, quotes may be prepared by project managers, sales representatives, directors, or corporate officers. Client contracts must be reviewed and signed by a corporate officer such as the Laboratory Vice President or his designee. A Contract Review Record serves to document and finalize this review process.

The designated project manager informs the client of the results of the review if it indicates any potential conflict, deficiency, lack of accreditation, or inability of the lab to the complete the work satisfactorily.

The client is informed of any deviation from the contract including the test method or sample handling processes. All differences between the request and the final contract are resolved and recorded before any work begins. It is necessary that the contract be acceptable to both the laboratory and the client.

The review process is repeated when there are amendments to the original contract by the client. The participating personnel are given copies of the amendments. The amendments are maintained with the original documentation by the project manager.

7.2 Documentation of Review

Formal requests and subsequent responses are filed in unique client-specific files. Records are maintained for every contract or work request, when appropriate. This includes pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract. Individual documents are stored as separate electronic files but are all cataloged by specific client number, account name and project name. All written correspondences pertaining to a project are also filed in the client files. Project modifications may be documented by placing comments on the Chain of Custody (COC) forms, memoranda placed in files or comments placed in the LIMS – Element DataSystem®.

Figure 7-1

PDC Laboratories Inc.
Peoria, IL
Contract Review Record

Date:_____

Client Name: _____

PDC Reviewer: _____

General Description of Services to be provided under this contract:

_____

_____

Length of Contract: _____

Dollar value of Contract:_____

Circle YES, NO, or NA as appropriate for the following: for any NO answers, elaborate in the comments section as appropriate.

1. Does the lab have the proper technical capability? YES NO N/A
2. Does the lab have adequate capacity? YES NO N/A
3. Does the lab have proper resources? YES NO N/A
4. Does the lab have the necessary accreditations/certification? YES NO N/A
5. Does the lab use the required test methods? YES NO N/A
6. Does the lab have the proper quality control measures? YES NO N/A
7. Will any work need to be subcontracted? YES NO N/A
   If yes, does the subcontractor meet all of these requirements? YES NO N/A

   Name of Subcontractor, and nature of subcontracted work.

   _____

8. Will the lab be required to collect samples? YES NO N/A
9. Does the lab have the necessary sample collection capabilities? YES NO N/A
10. Will the lab be able to meet the turnaround time required YES NO N/A
11. Are there any special reporting requirements? YES NO N/A

Comments: _____

_____

Final decision for contract acceptance YES NO Initials_____
Attach additional comments/pages if necessary.

Return completed form to Laboratory Vice President or Designee.

Section 8

SUBCONTRACT OF ENVIRONMENTAL TESTS
(TNI V1:M2 – Section 4.5)

A subcontract laboratory is defined as a laboratory external to this laboratory, or at a different location than the address indicated on the front cover of this manual, that performs analyses for this laboratory.

When subcontracting analytical services, the laboratory assures work requiring accreditation is placed with an appropriately accredited laboratory or one that meets applicable statutory and regulatory requirements for performing the tests. The laboratory ensures that the subcontract laboratory understands the requirements and will meet the same commitments made to the client by the primary laboratory except in the case where a client or a regulating authority specifies which subcontractor is to be used.

8.1 Procedure

Determination of Need

During the initiation of a project, a project manager will determine if there is a need to subcontract. Subcontracting is typically needed when PDC Laboratories, Inc. does not perform the requested analysis or does not possess the necessary accreditation for the requested analysis and/or the end user requirements for the resultant data. PDC Laboratories, Inc. shall advise the client in writing of its intention to subcontract any portion of the testing to another party. When internal capacity or equipment issues occur, the Laboratory Vice President will authorize that work which needs to be subcontracted by the project manager.

Analyses that are routinely subcontracted include: radiochemistry, dioxins/furans (soils), asbestos in drinking water, air matrix adsorbent materials, geotechnical (physical properties of soils), suitability, sieve, BTU, coal testing, methane/ethane, yeast and mold, low-level mercury, tannins, PIXE, and carbamates in solid samples by SW-846 Method 8321.

Choice of Subcontract Laboratory

Project managers are responsible for the selection of the subcontract laboratory and should be consistent in their choice. The subcontract laboratory must have the capability and capacity to perform the needed analysis and to submit the results of the tests performed. The subcontract laboratory must possess the appropriate accreditation or certification as required for the end user of the data, if applicable. When a laboratory subcontracts any part of the testing covered under TNI, this work must be sent to a laboratory accredited under TNI, or with a laboratory that meets applicable statutory and regulatory requirements.

The Director of Sample Logistics maintains the list of subcontractors.

The project manager will obtain the cost of the subcontracted work, and the anticipated turnaround time for the subcontracted work.

Project Setup

The project manager is responsible for ensuring that the Sample Control Department is aware of the need to subcontract samples by giving advance notice or by putting the appropriate Element DataSystem® analytes in a schedule for those samples.

Sample Login

All subcontract work must be tracked through the Element DataSystem®. Subcontract analytes in Element start with "01-…" and are assigned to Department 304. If the subcontracted work is known at the time of the original login, the Sample Control Department will add the appropriate codes to the login. If the need to subcontract develops at a later time, the project manager will add the subcontract code to the login. In instances where the sample must be sent directly to the subcontract laboratory from the client, the project manager is responsible for getting appropriate subcontract codes entered and updated in Element.

Shipping

The Sample Control Department is responsible for splitting the sample (if necessary), packaging, filling out the Chain-of-Custody (COC), filling out a Purchase Order (PO), and shipping the samples to the subcontract laboratory. The only sample information provided to the subcontract laboratory is the PDC Element DataSystem® assigned sample number, date and time of collection, and matrix. If a sample is contracted for compliance, it may be necessary to provide more information. Copies of the PO are given to the Director of Sample Logistics. After filling out the appropriate paperwork, the Sample Control department will update the status of the subcontract code in Element to "shipped" status when the sample(s) ship. The Director of Sample Logistics will run a worklist from Element at least daily to verify that subcontracted samples were shipped. Any samples showing up on the worklist will indicate they have not been shipped and the Director of Sample Logistics will question the appropriate project manager as to the status of the project.

If a subcontract code is added after the initial login creation, the project manager is responsible for informing the Director of Sample Logistics that the sample needs to be shipped.

Reporting

When the final report is submitted to the client, the original subcontractor's report must be sent to the client. The PDC Element DataSystem® generated report should include the subcontracted analytes and indicate "Subcontracted Report Attached". In some instances, a transfer file may be used to incorporate subcontracted laboratory data into the body of the standard LIMS report. However, the subcontracted laboratory has to use a LIMS compatible with the Element Data System® and the results must be appropriately identified. Copies of all reports and COCs will be kept in the client report file.

Invoicing

The project manager is responsible for assigning the correct pricing in Element for the subcontracted samples. These costs should be reviewed carefully since some subcontract codes in Element are generic codes that can be used under different circumstances.

Interlaboratory Transfer of Samples Between Network Laboratories

The email/telephone notification portions of this protocol are applicable when transferred samples arrive at the receiving laboratory with less than five calendar days before the expiration of hold time and/or due date. The login/labeling/statuses/COC portions are applicable for all transfers between labs.

The facility receiving the sample initially will log the samples into the Element DataSystem®, assign the appropriate project, testing analytes, complete the COC paperwork, and label the bottles. For those analyses to be performed at the other facility, the appropriate analyte codes need to be entered into Element and the correct department status set. When the facility doing the analysis changes after the initial login, the facility originally doing the analysis needs to change the analysis to the receiving facility's analysis and set the status appropriately.

For short notice samples being shipped from St. Louis, a representative from Client Services will email the appropriate receiving laboratory department manager with the details of what is coming. **A phone call will precede the email**.

The Laboratory Vice President, Senior Project Manager, and Laboratory Supervisor must be copied on the emails. The Sample Control staff at each facility must also be included on the email.

The details of the email should include how many samples are being sent, the sample matrix, when they should arrive, what testing parameters are required, what the requested completion date is, and any other special instructions or pertinent information. The appropriate department manager will respond to all parties via email, acknowledging receipt of the email and informing the sending laboratory whether the requested time frames can be met and if not, what can be done. If the Peoria department manager is out of the office, the Senior Project Manager or Laboratory Vice President will follow up on the email.

For samples being sent from Peoria the same protocol applies.

The Laboratory Supervisor and Client Services must be copied on the emails. The Sample Control staff at each facility must also be included on the email.

If the St Louis contact person is out of the office, a representative of the St. Louis Client Service Department will follow up on the email.

For any instances where this protocol applies to samples being shipped to or from the Springfield lab the contact person is the Laboratory Supervisor or in his absence, the Administrative Assistant.

Section 9

PURCHASING SERVICES AND SUPPLIES
(TNI V1:M2 – Section 4.6)

The laboratory ensures that purchased supplies and services that affect the quality of environmental tests are of the required or specified quality by using approved suppliers and products. Services include balance calibration, NIST thermometer calibration, autoclave maintenance, Class 1 weight calibrations and service contracts for instrumentation.

The laboratory has procedures for purchasing, receiving, and storage of supplies that affect the quality of environmental tests.

9.1 Procedure

General authority for purchasing rests with the Vice President, Directors and Department Managers. Authority for specific purchasing may be delegated to other staff by these management employees and to the designated Purchasing Agent who deals primarily with laboratory chemicals, reagents and consumables.

Certain supplies and services are unique to a particular section of the laboratory. Purchasing is administered through that particular section.

Quality Assurance**:** Proficiency Testing (PT) samples; balance calibrations; NIST thermometer calibrations; Class 1 weight calibrations

Sample Logistics: sample containers (except microbiological specific sample containers); subcontracted samples; shipping supplies; vehicle repair and maintenance

Facility: supplies – lighting, filters for air handling units, laboratory repair parts and supplies; services – HVAC repair, water purification system and maintenance, wastewater treatment maintenance, security, hazardous waste and lab pack

Chemistry: general supplies, capital purchases, building modifications and repairs; equipment

Microbiology: microbiological specific sample containers, all microbiological supplies; yearly servicing of microscopes, repair/maintenance of autoclaves, microbiological incubators.

(Note: The Microbiology Section is certified by the Illinois Department of Public Health)

IT: computers and peripherals; miscellaneous hardware; software and licenses

Field Sampling: in-line filters, disposable bailers, rental equipment (if needed), replacement probes for pH and specific conductance, depth to water meters, submersible pumps and vehicle repair and maintenance

The current revision of SOP#900-Purchasing, PURCHASING SERVICES and SUPPLIES provides an overview of those processes used to ensure that purchased supplies and services that affect the quality of environmental tests are of the required or specified quality by using approved suppliers and products.

Evaluation of suppliers is accomplished by ensuring the supplier ships the product or material ordered and that the material is of the appropriate acceptable quality by signing packing slips or other supply receipt documents after inspection. The purchasing documents contain the data that adequately describes the services and supplies ordered. The description may include type, class, grade, identification, specifications or other technical information.

The supplies received are inspected for breakage, leaks or any other damage. The supplies and chemicals are checked for expiration date, concentration, grade, and storage conditions. The supplies received are stored according to manufacturer's recommendations, laboratory SOPs or test method specifications.

Any documents received with the supplies and services including specifications, certificates of analyses, warranties, maintenance records, calibration records etc are kept on file by the responsible Director or Department Manager.

The purchased supplies and reagents that affect the quality of the tests are not used until they are inspected or otherwise verified as complying with requirements defined in the test method.

9.2 Approval of Suppliers

Each purchasing agent maintains a list of approved suppliers for those items for which they are responsible.

Evaluation and selection of suppliers and vendors is performed, in part, on the basis of the quality of their products, their ability to meet the demand for their products, the overall quality of their services, their past history and competitive pricing. This is achieved through evaluation of objective evidence of quality furnished by the supplier, which can include certificates of analysis, recommendations, and proof of historical compliance with similar programs for other clients. To ensure that quality critical consumables and equipment conform to specified requirements, all purchases from specific vendors are approved by a member of the management staff.

Evaluation of suppliers is accomplished by ensuring the supplier ships the product or material ordered and that the material is of the appropriate quality. This is documented by signing off on the packing slips or other supply receipt documents.

Section 10

SERVICE TO THE CLIENT
(TNI V1:M2 – Section 4.7)

The laboratory collaborates with clients and/or their representatives in clarifying their requests and in monitoring laboratory performance related to their work. Each request is reviewed to determine the nature of the request and the laboratory's ability to comply with the request within the confines of prevailing statutes and/or regulations without risk to the confidentiality of other clients.

10.1 Client Confidentiality

All reports and related information provided to and paid for by clients of PDC Laboratories, Inc. in connection with PDC Laboratories, Inc. are the property of the client. The laboratory confidentiality policy is to not divulge or release any information to a third party without proper authorization. The term “Confidential Information” means information concerning PDC Laboratories, Inc. which is not generally known to those engaged in similar businesses (realm of public domain) and that is used or obtained by PDC Laboratories, Inc. in connection with its business. Specifics concerning the term “information” and other procedural details may be found in the SOP, CLIENT CONFIDENTIALITY.

No such property will be provided to any other party, by any means (verbal, written, or electronically) or discussed with another party without the expressed consent of the client. PDC Laboratories, Inc. reserves the right to request written authorization to release information. Third party requests for data and information are referred to the client. Data and records identified as proprietary, privileged, or confidential are exempt from disclosure.

No employee shall release, or cause or allow the release of, information to the communications media, except as required by law, concerning the existence or terms of services, including the identification of the client, the samples, or the general description, characteristics, or constituents of the samples, without, in each case, securing the prior consent of the client. Actions contrary to this will result in disciplinary action with possible termination. It is PDC Laboratories, Inc.’s policy to fully comply with any court issued subpoenas for information. Such requests are to be brought to the attention of the Laboratory Vice President or Senior Project Manager for referral/consultation with the company legal representative prior to the release of the information. Affected clients must be advised that such a request (subpoena) has been issued.

When providing information to clients from internal sources that contain other client’s information, the identity of the other clients must be withheld. This practice includes preparing QC Summaries, data packages, and any other raw data. To avoid the inadvertent release of Confidential Information, the Director of Quality Assurance or designee should review the information prior to submittal to the client.

In the event of an inadvertent release of information (wrong address on envelope, switched envelopes, incorrect email address, etc.) every effort should be made to have the original information returned to PDC Laboratories, Inc. The source of the inadvertent release will be investigated, the root cause determined, and the resultant corrective action taken, documented and verified.

Electronic transfer of data or any project related information from PDC Laboratories, Inc. via facsimile (fax) or electronic mail systems (e-mail) must be accompanied by the following statement:

> **"This communication including any attachments is for the exclusive and confidential use of the designated recipient and any other distribution or use is unauthorized and strictly prohibited. If you have received this communication in error, please notify the sender by replying to this message and then deleting the message from your system."**

If so notified, the appropriate laboratory representative will decide the further action to be taken.

Note: Disregard of these client confidentiality procedures will result in disciplinary action which may include any or all of the following: verbal warning, written warning, unsatisfactory performance review, salary reduction considerations, termination, or potential legal actions brought in a court of law by outside parties.

10.2 Client Support

Communication with the client, or their representative, is maintained throughout the project to provide proper instruction and for any modification in the testing. Dedicated project managers are available to discuss any technical questions or concerns the client may have.

Clients may request tours of the facility during the bid process, prior to the initiation of a project or during the project. The client, or their representative, is provided reasonable access to laboratory areas for witnessing testing as necessary.

Potential problems, delays or major deviations to the testing are communicated to the client as soon as possible by the overseeing project manager or designee. The form of communication is dependent on the requirements and availability of the client (telephone, email, or text) and the urgency of the situation.

All correspondence between the client and the laboratory that establishes or modifies what is to be done on a project must be documented and retained. Formal requests and subsequent responses are filed in unique client or project specific files. Various forms of documentation may be used on a given project. Project modifications may be documented by placing comments on the chain-of-custody (COC) form, memos placed in the files, or comments placed in the LIMS. Project managers are

encouraged to use telephone logs to document their verbal discussions with clients; however, any form of written documentation such as email is acceptable.

The laboratory will provide the client with all requested information pertaining to the analysis of their samples. An additional charge may apply for additional data/information that was not requested prior to the time of sample analysis or previously agreed upon.

10.3 Client Feedback

The laboratory seeks both negative and positive feedback following the completion of projects and periodically for ongoing projects through the use of review of final reports with the clients as necessary and by the use of surveys to gauge client satisfaction with the laboratory's services. Feedback provides acknowledgement, corrective actions where necessary, and opportunities for continuous improvement.

Negative client feedback is documented as a client complaint (see Section 11 – "Complaints").

Section 11

COMPLAINTS
(TNI V1:M2 – Section 4.8)

The purpose of this Section is to assure that client complaints are addressed and corrected. A complaint is a client's formal expression of dissatisfaction with the performance of one or more of the laboratory's activities. Requests to verify results or analytical data are also included within this definition. The source of the complaint may be either a client or an employee of the laboratory. All client complaints are documented by the person receiving the complaint and are addressed to the Quality Assurance Department. Examples of complaints may include bottle shipment errors, missed sample hold times, calculation errors, data that does not make sense for the analysis performed, incorrect analyses performed, typographical errors, accidentally omitted results or late reports. Complaints provide the laboratory an opportunity to improve laboratory operation and client satisfaction.

Records shall be maintained of all complaints so that the QA Department can track and monitor the complaint process through the investigation and corrective action stages. Lack of documented complaints also prevents management during the managerial review process from determining the suitability of the complaint process and making improvements in laboratory operations and the management system based on an analysis of received complaints.

The complaints are reviewed and investigated by the QA Department and an appropriate action is determined. If it is determined that the complaint has merit, the procedures outlined in Section 14 – Corrective Action are utilized. If it is determined that a complaint is without merit, it is documented, and the client is contacted by the appropriate project manager to explain why no further investigation or corrective action is warranted.

A warranted complaint will be considered resolved when the following conditions are met:

a. all of the facts concerning the complaint have been gathered from the client or party who initiated the complaint, the project files, the project manager, and any employee(s) directly involved,
b. after a review of the facts of the complaint, a decision has been reached and corrective action has been proposed, if necessary, to correct any problems,
c. the proposed corrective action has been taken, and
d. all forms documenting this process have been completed, signed by the appropriate member of management, and filed with the QA Department.

Specific procedural details may be found in the SOP, CLIENT COMPLAINT RESOLUTION.

A complaint such as a concern that data is repeatedly late should be reviewed for preventive action (see Section 15 – "Preventive Action") to minimize a future occurrence.

Section 12

CONTROL OF NON-CONFORMING ENVIRONMENTAL TESTING WORK
(TNI V1:M2 – Section 4.9)

Non-conforming work is work that does not meet acceptance criteria or requirements. Nonconformances can include departures from standard operating procedures or test methods or unacceptable quality control results (see Section 27 – "Quality Assurance for Environmental Testing"). Identification of non-conforming work can come through client complaints, quality control elements, instrument calibration, evaluating consumable materials, staff observation, final report review, management reviews and internal or external audits.

12.1 Exceptionally Permitting Departures from Documented Policies and Procedures

Departures from laboratory procedures are approved by a Department Manager, the responsible Project Manager and by a member of the QA Department. The departure is documented on a Data Exception Report with a concurring signature of from each department. Planned departures from procedures or policies do not require audits or investigations but must be documented as a nonconformance that was approved by management.

Examples of departures may include:

- the required sample volume is not received, and the client wants the analysis completed anyway. The departure would be documented and the data would be qualified if necessary.

- insufficient sample volume is available for a rerun, where holding time has been exceeded, or where sample data are not affected by the nonconformance.

12.2 Non-Conforming Work

The lab policy for control of non-conforming work is to identify the non-conformance, determine if it will be permitted, and take appropriate action. Each case needs to be considered on its own merit. All employees have the authority to stop work on samples when any aspect of the process does not conform to laboratory requirements.

The responsibilities and authorities for the management of non-conforming work are detailed below. The procedure for investigating and taking appropriate corrective actions of non-conforming work is described in Section 14 – "Corrective Actions". Section 14.3 describes procedures for Technical Corrective Actions. Formal corrective action procedures must be followed for non-conforming work that could reoccur (beyond expected random QC element failures) or where there is doubt about the laboratory's compliance to its own policies and procedures.

The investigation and associated corrective actions of non-conforming work involving alleged violations of the company's Ethics and Data Integrity policies must follow the procedures outlined in Section 19 – "Data Integrity Investigations".

The laboratory evaluates the significance of the non-conforming work, and takes corrective action immediately. The client is notified if their data has been impacted. The laboratory allows the release of non-conforming data only with approval by the appropriate Department Manager or the QA Department on a case-by-case basis. Non-conforming data is clearly identified in the final report (see Section 28 – "Reporting the Results") through the use of qualifiers.

The discovery of a nonconformance for results that have already been reported to the client must be immediately evaluated for significance of the nonconformance, its acceptability to the client, and determination of the appropriate corrective action.

Corrective action for routine, non-recurring exceedances is documented on data worksheets, in logbooks, or on Data Exception Reports. More serious corrective actions (non-conforming work that could reoccur or where there is doubt that the laboratory is in compliance with its own policies and procedures) will require a formal investigation and corrective action process that includes documentation through the use of a Corrective Action Form.

12.3 Stop Work Procedures

Personnel **must** notify the appropriate Department Manager of any nonconformance that is a deviation from normal laboratory practices. The Department Manager reviews the significance of the nonconformance and develops a course of action. If data are questionable, the Director of Quality Assurance or designee must be involved in the review and the affected clients are notified by the responsible project manager.

When an investigation of nonconformance indicates that the cause of the nonconformance requires that a method be restricted or not used until modifications are implemented, the Laboratory Vice President, Director of Quality Assurance or Department Manager will immediately notify all personnel of the suspension or restriction. The laboratory will hold all relevant reports to clients pending review. The Director of Quality Assurance or designee must be involved in the resolution of the issue and must verify that the issue is resolved before work may resume. The Department Manager and Director of Quality Assurance will document the issue, root cause and resolution using the corrective action procedures described in Section 14 – "Corrective Action".

The reporting of non-conforming work involving alleged violations of the company's Ethics and Data Integrity policies must be reported to the Director of Quality Assurance or the Laboratory Vice President. Procedures described in Section 19 – "Data Integrity Investigations" are followed.

Resumption of work after work has been stopped is authorized by the Laboratory Vice President, the Director of Quality Assurance or Department Manager. Personnel are notified by the Department Manager when resumption of work is authorized.

Section 13

IMPROVEMENT
(TNI V1:M2 – Section 4.10)

Improvement in the overall effectiveness of the laboratory management system is a result of the implementation of the various aspects of the laboratory's management system: quality policy and objectives (Section 5 – "Management"); internal auditing practices (Section 17 – "Internal Audits"); the review and analysis of data (Section 27 – "Quality Assurance for Environmental Testing"); the corrective action (Section 14 – "Corrective Action") and preventive action (Section 15 – "Preventive Action") process; and the annual management review of the quality management system (Section 18 – "Management Reviews") where the various aspects of the management/quality system are summarized, and evaluated and plans for improvement are developed.

Section 14

CORRECTIVE ACTION
(TNI V1:M2 – Section 4.11)

Corrective action is the action taken to eliminate the causes of an existing non-conformity, defect, or other undesirable situation in order to prevent recurrence.

Deficiencies cited in external assessments, internal quality audits, data reviews, client feedback or complaints, control of nonconforming work, failed proficiency testing (PT) samples or managerial reviews are documented and require corrective action. Corrective actions taken are appropriate for the magnitude of the problem and the degree of risk.

14.1 General Procedure

Four basic steps guide the corrective action process:

- Clearly identify the problem: What happened?
    - Be specific. Define the problem or issue as much as possible
    - Ask clarifying questions as needed
        - Why did this occur?
        - What contributed to the problem?
        - How did this happen?
        - Has this occurred before?
        - Why did the previous solution fail?
        - Which one of the quality systems is affected?
- Identify the cause(s): Why did it happen?
    - Brainstorm possible causes. At this point, list all possible causes (do not evaluate or eliminate any).
    - Consider what data can confirm or disprove each possible cause: then collect and analyze that data to eliminate possible causes that are not supported by the data
    - Identify the cause(s) that is the most compelling explanation, based on all available data.
    - Ask “Why?” again!
    - Continue for a minimum of five times
    - Show a logical relationship of each response to the one that preceded it
    - Continue to ask “Why?” until:
        - The Root Cause is reached
        - A problem that is not correctable is reached
        - There is insufficient data to continue
- Develop a plan: What will be done to keep the outcome from recurring?

  - Include:
    - Steps to take
    - A timeline
    - Resources that will be needed
    - Person/people responsible for each step

- Monitor the plan: How will the change be validated and verified?

  - Indicate a timeline for each and assign a person/people responsible for each:
    - What assessment or data will be used to determine if the plan is being implemented consistently?
    - What assessment or data will be used to determine if the plan is being effective at addressing the root cause?
    - What assessment or data will be used to determine if the plan is being successful at changing the outcome?

The laboratory uses Data Exception Reports (Figure 14-1), Corrective Action Forms (Figure 14-2) and Proficiency Testing Sample Data Review/Corrective Action Reports (Figures 14-3a and b) to document and track corrective actions.

Department Managers, Project Managers, Directors, members of the Quality Assurance Department, and the Laboratory Vice President are responsible for initiating corrective action on routine data reviews where a nonconformance is found that could reoccur (beyond expected random QC failures) or where there is doubt about the compliance of the laboratory to its own policies and procedures. Department Managers in conjunction with members of the Quality Assurance (QA) Department are responsible for monitoring and recording the corrective action. In addition, the appropriate Project Manager may become involved if the corrective action is client-specific.

14.1.1 Root Cause Analysis

Root Cause Analysis (RCA) is a structured evaluation method that is used to address a problem or a nonconformance in order to get to the “root” or underlying cause of the problem. The method is used to correct or eliminate the cause of a problem and to prevent the problem from recurring. Root Cause Analysis should continue until organizational factors have been identified or until data is exhausted.

Root Cause is the cause or contributing factor that produced the fundamental breakdown or failure of a process which, when corrected, prevents a recurrence of the problem. In other words, once a root cause is identified and fixed, the problem goes away and doesn’t come back. If a poor job is done identifying the root cause of a problem, time and resources are wasted in putting “Band-Aids” on the symptoms of the problem because the “true” problem will never really go away.

Care should be taken when using RCA to discover underlying problems since:

- often there is no clear, obvious cause that immediately jumps out or there are many possible causes such that it becomes difficult to identify the meaningful one,
- some RCA techniques may provide easy answers that are either incomplete or wrong (but easy to find),
- the process may become tedious since one must ask “why” and then to each answer to that question ask “why” again and again until the fundamental cause(s) have been identified,
- blame is an obstacle,
- guidance may be needed to investigate human performance problems,
- there is no way to know for certain that the fundamental root cause has been identified until a corrective action is planned, and
- a perfectly executed RCA may not lead to the desired change the first time.

RCA is a tool to be used to reach the source of a problem but, as with any tool, it requires understanding and skill in applying the various techniques of the method.

Records are maintained by the QA Department of any nonconformance requiring corrective action to show that the root cause(s) was investigated, and includes the results of the investigation.

Where there may be non-systematic errors and as such the initial cause is readily identifiable or expected random failures (e.g. failed quality control), a formal root cause analysis is not performed and the process begins with selection and implementation of corrective action (also see Section 14.3 “Technical Corrective Actions”).

14.1.2 Selection and Implementation of Corrective Actions

Where uncertainty arises regarding the best approach for analysis of the cause of exceedances that require corrective action, appropriate personnel will recommend corrective actions that are appropriate to the magnitude and risk of the problem and that will most likely eliminate the problem and prevent recurrence.

The Laboratory Vice President, appropriate Director or Department Manager ensures that corrective actions are discharged within the agreed upon time frame.

14.1.3 Monitoring of Corrective Action

Members of the QA Department will monitor implementation and documentation of the corrective action to assure that the corrective actions were effective.

14.2 Additional Audits

Where the identification of nonconformances or departures from normal lab procedures cast doubt on the laboratory's compliance with its own policies and procedures or on its compliance with the TNI Standard, the laboratory ensures that

the appropriate areas of activity are audited in accordance with Section 17 – "Internal Audits" as soon as possible.

In many cases, these additional audits are follow-ups after corrective action has been implemented to ensure its effectiveness. These are done when a serious issue or risk to the laboratory has been identified.

14.3 Technical Corrective Action

Sample data associated with a failed quality control are evaluated for the need to be reanalyzed or qualified. Unacceptable quality control results are documented, and if the evaluation requires cause analysis, the cause and solution are recorded (also see Section 12 – "Control of Nonconforming Environmental Testing Work"*).* Analysts routinely implement corrective actions for data with unacceptable QC measures. First level correction may include re-analysis without further assessment or qualifying the data if re-analysis is not possible. If the test method SOP addresses the specific actions to take, they are followed. Otherwise, corrective actions start with assessment of the cause of the problem.

Corrective action for non-systematic errors or expected random failures is documented on Data Exception Reports. Corrective actions for nonconformances that may reoccur (beyond expected random QC failures) or where there is concern that the laboratory is not in compliance with its own policies and procedures require that a Corrective Action Report be completed (see Section 14.1).

Department Managers and the QA Department review the Corrective Action Reports and suggest improvements, alternative approaches, and procedures where needed.

If the data reported are affected adversely by the nonconformance, the affected data is clearly identified in the report and the client is notified.

Figure 14-1: Data Exception Report

PDC Laboratories, Inc. – Data Exception Report
YEAR – DER – Department – Incident Number

Section 1: Source or Nature of the Nonconformance

Analytical Section: Inorganics ☐ Metals Prep. ☐ Metals ☐ Organics Ext. ☐
GC ☐ HPLC ☐ GC/MS ☐ HRGC/HRMS ☐

Client: _____ Sample #: _____

Method/Parameter: _____ Matrix: _____

Problem Incurred:
Hold time ☐ Duplicate ☐ MS/MSD ☐ Limited Sample ☐ Surrogate ☐
BS ☐ Matrix Interference ☐ Blank ☐ Instrument Problem ☐ Other ☐

Explanation: _____

Analyst: _____ Date: _____

Section 2: Department Manager Investigation/Corrective Action/Resolution

Manager: _____ Date: _____

Section 3: Acknowledgement of Nonconformance and Corrective Action

Depart. Manager: _____ Date: _____
Project Manager: _____ Date: _____
QA Director: _____ Date: _____

Section 4: To be completed by the Project Manager

Problem handled in accordance with project QC guidelines: Yes ☐ No ☐
Data acceptable for release to client: Yes ☐ No ☐
Client Contacted: Yes ☐ No ☐ Contact Name: _____ Date Contacted: _____
Required Action: _____

Project Manager: _____ Date: _____

Section 5: To be completed by QA

Problem handled in accordance with Quality System Procedure: Yes ☐ No ☐
Comments: _____

QA Director: _____ Date: _____

Section 6: Routing (original form to QA if hardcopy)

Raw Data Box ☐ Electronic Folder ☐ Department Manager ☐ Project Manager ☐ QA ☐

Figure 14-2: Corrective Action Report

PDC Laboratories, Inc. – Corrective Action Form
YEAR – CAF – Department – Incident Number

Originated by:	**Date:**
Department:	**Contact:**
Response Due Date:	**Completed:**

A. Departure from Quality System Policy or Procedure and Investigation

Describe the departure (What was the departure from policy? Why?)

B. Departure from Standard Operating Procedure (SOP) and Investigation

Describe the departure (What was the departure from the SOP? Why?)

C. Other Problems and investigation

Describe the situation (How did you know something was wrong?)

Corrective Action Mechanism

List any activities or checks performed to identify the source and resolve the problem.

Documentation of Resolution

What changes have been made to prevent the problem from reoccurring?

Data Qualification

Identify affected samples and qualifier used

QA Verification of Corrective Action

Signature: Date:

Figure 14-3a: PT Sample Data/Corrective Action Report – Organics

PDC Laboratories, Inc.
Proficiency Testing (PT) Sample Data Review/Corrective Action Report
YEAR – STUDY – DRCA – ORG – INCIDENT NUMBER

ORGANICS

Study: _____ Date Response Due: _____

Sample: _____ Parameter: _____

Reported Value: _____ True Value: _____

Acceptance Range: _____

Summary of Sample and QC Data
(Please indicate appropriate answer-pass/fail, % recovery with acceptance criteria)

Analyst: _____ Instrument: _____

Method: _____ Initial Calibration (% RSD or r): _____

ICV: _____ IB: _____ PEM: _____

LPC: _____ S/N: _____ MDLCHK: _____

PRL: _____ BFB: _____ DFTPP: _____

CCV before sample: _____ CCB before sample: _____

CCV after sample: _____ CCB after sample: _____

Method Blank: _____ Blank Spike: _____

Blank Spike Duplicate: _____ MS/MSD Spike: _____

Explanation /Possible Source of Error: _____

_____

_____

_____

Corrective Measures Taken: _____

_____

_____

_____

Department Manager: _____ Date: _____

QA Department: _____ Date: _____

Corrective Action Verified - QA Dept. _____ Date: _____

Figure 14-3b: PT Sample Data/ Corrective Action Report – Inorganics

PDC Laboratories, Inc.
Proficiency Testing (PT) Sample Data Review/Corrective Action Report
YEAR – STUDY – DRCA – INORG – INCIDENT NUMBER

INORGANICS

Study: _____ Date Response Due: _____

Sample: _____ Parameter: _____

Reported Value: _____ True Value: _____

Acceptance Range: _____

Summary of Sample and QC Data
(Please indicate appropriate answer-pass/fail, % recovery with acceptance criteria)

Analyst: _____ Instrument: _____

Method: _____ Initial Calibration (% RSD or r): _____

ICV: _____ ICB: _____

CCV before sample: _____ CCB before sample: _____

CCV after sample: _____ CCB after sample: _____

Method Blank: _____ Blank Spike: _____

Blank Spike Duplicate: _____ Duplicate or MS/MSD Spike: _____

ICS before/after: _____ Post Digestion Spike: _____

Explanation /Possible Source of Error: _____

Corrective Measures Taken: _____

Department Manager: _____ Date: _____

QA Department: _____ Date: _____

Corrective Action Verified - QA Dept. _____ Date: _____

Section 15

PREVENTIVE ACTION
(TNI V1:M2 – Section 4.12)

Preventive action is a pro-active process to identify opportunities for improvement rather than simply a reaction to the identification of problems or complaints. Preventive Action is the next logical step after a permanent root cause corrective action. A root cause corrective action is the action taken to eliminate the error on an affected process. A preventive or systemic corrective action is the action to prevent the error from recurring on any process.

Preventive action includes, but is not limited to: use of control charts to review QC data to identify quality trends, regularly scheduled staff quality meetings to ensure staff is knowledgeable in quality procedures, review of client feedback to look for improvement opportunities, review of proficiency testing data to look for analytes that were nearly missed, annual managerial reviews, scheduled instrument maintenance, and other actions taken to prevent problems.

When improvement opportunities are identified or if preventive action is required, action plans are developed, implemented and monitored to reduce the likelihood of the occurrence of nonconformities.

Procedures for preventive actions include the initiation of such actions and subsequent monitoring to ensure that they are effective.

All personnel have the authority to offer suggestions for improvements and to recommend preventive actions, however management is responsible for implementing preventive action.

A Request For Change (RFC) form and completion instructions are available from the Quality Assurance Department to document the request, the formal review by the Department Managers, Laboratory Vice President and Director of Quality Assurance, and any actions taken.

Section 16

CONTROL OF RECORDS
(TNI V1:M2 – Section 4.13)

Records are a subset of documents, usually data recordings that include annotations, such as daily refrigerator temperatures posted to a laboratory form, lists, spreadsheets, or analyst notes on a chromatogram. Records may be on any form of media, including electronic and hard copy. Records allow for the historical reconstruction of laboratory activities related to sample-handling and analysis.

The laboratory maintains a record system appropriate to its needs, records all laboratory activities and complies with applicable standards or regulations as required. Records of original observations and derived data are retained to establish an audit trail. Records help establish factors affecting the uncertainty of the test and enable test repeatability under conditions as close as possible to the original.

16.1 Records Maintained

Records of all procedures to which a sample is subjected while in the possession of the laboratory are kept. The laboratory retains all original observations, calculations and derived data (with sufficient information to produce an audit trail), calibration records, personnel records and a copy of the test report for a minimum of five years from generation of the last entry in the records. At a minimum, the following records are maintained by the laboratory to provide the information needed for historical reconstruction:

i) all raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' worksheets and data output records (chromatograms, strip charts, and other instrument response readout records);

ii) a written description or reference to the specific method(s) used, which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value (a copy of all pertinent Standard Operating Procedures);

iii) laboratory sample ID code;

iv) date of analysis;

v) time of analysis is required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., extractions and incubations);

vi) instrumentation identification and instrument operating conditions/parameters (or reference to such data);

vii) all manual calculations (including manual integrations);

viii) analyst's or operator's initials/signature or electronic identification;

ix) sample preparation, including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;

x) test results (including a copy of the final report);

xi) standard and reagent origin, receipt, preparation, and use;

xii) calibration criteria, frequency and acceptance criteria;

xiii) data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;

xiv) quality control protocols and assessment;

xv) electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;

xvi) method performance criteria including expected quality control requirements;

xvii) proficiency test results;

xviii) records of demonstration of capability for each analyst;

xix) a record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record;

xx) correspondence relating to laboratory activities for a specific project;

xxi) corrective action reports;

xxii) preventive action records;

xxiii) copies of internal and external audits including audit responses;

xxiv) copies of all current and historical laboratory SOPs, policies and *Quality Manual*s or Plans;

xxv) sample receiving records (including information on any interlaboratory transfers);

xxvi) sample storage records;

xxvii) data review and verification records;

xxviii) personnel qualification, experience and training records;

xxviv) archive records; and

xxviv) management reviews.

16.2 Records Management and Storage

The laboratory maintains a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage, and reporting. Data is recorded immediately and legibly in permanent black ink (data generated by automated data collections systems is recorded electronically.) Corrections are initialed and dated with the reason noted for corrections (other than transcription errors) as needed. A single line strikeout is used to make corrections so that the original record is not obliterated. Corrections made to electronic documentation are tracked through the audit trail function of the LIMS.

The data stored in the Element DataSystem® (LIMS) is backed-up daily off-site (cloud storage). All other data system back-ups are done in-house daily.

Records, including electronic records, are easy to retrieve, legible, and protected from deterioration or damage; held secure and in confidence; and are available to accrediting bodies for a minimum of five years or as required by regulation or contract. Records that are stored only on electronic media are supported by the hardware and software necessary for their retrieval. Access to protected records is limited to the Corporate IT Manager and to the Laboratory Systems Administrator to prevent unauthorized access or amendment.

Additional information regarding control of data is included in Section 22.5 – “Control of Data”.

The current revision of SOP-GEN-HrdcpyRecStrge, Hardcopy Record Storage, Retrieval and Disposal details the storage, retrieval and disposal procedures for non-electronic records of raw analytical data and the hardcopy records of client report files. Archived records have limited access and are checked out through an access log. Hardcopy quality records are maintained within the QA Department. Electronic versions are stored in a shared network folder on a laboratory file server.

Records less than one and one-half years old are stored on-site at the facility. Records older are stored at a secure off-site facility. Records older than five years are destroyed by a third party service which provides confidential record disposal. However, records deemed to be “historical” may be kept for greater than five years. The record disposal service provides a certificate of records destroyed upon completion of the destruction.

In the event that the laboratory transfers ownership or goes out of business, records are maintained or transferred according to client instructions as per the current revision of SOP-GEN-RcrdTrnsfer, Record Transfer Procedure.

In the event that PDC Laboratories, Inc. purchases another laboratory or is purchased by another laboratory, the transaction will include an agreement that contains a statement detailing who is to retain and be responsible for the analytical records. In the event that PDC Laboratories, Inc. goes out of business, Coulter Companies, Inc. (the laboratory's parent company) will retain the records.

Appropriate regulatory and state legal requirements concerning laboratory records shall be followed.

16.3 Legal Chain of Custody Records

Evidentiary sample data are used as legal evidence. Procedures for evidentiary samples can be found in the current revision of SOP-GEN-InternalCOC, Internal Chain of Custody. In cases where the custody of a sample must be documented, this procedure details the steps taken to provide the means of meeting this objective. A sample is in someone's custody if it is in their physical possession, it is in their view after being in their physical possession, and it was in their physical possession and is now secured so that no one can tamper with it, or it is kept in a secure area restricted to authorized personnel only. All steps must be documented with sample number, container type, date/time of transfer, and initials.

Section 17

AUDITS
(TNI V1:M2 – Section 4.14)

Audits measure laboratory performance and verify compliance with accreditation/ certification and project requirements. Audits specifically provide management with an on-going assessment of the management system. They are also instrumental in identifying areas where improvement in the management/quality system will increase the reliability of data. Audits are of four main types: internal, external, performance, and system. Section 17.5 discusses the handling of audit findings.

17.1 Internal Audits

Annually, the laboratory performs a series of internal audits as documented in the current revision of SOP-GEN-Audit, Internal Performance and Quality System Audits. These audits verify compliance with the requirements of the management/quality system, including analytical methods, SOPs, the *Quality Manual*, ethics policies, data integrity, other laboratory policies, and the TNI Standard. Additional areas of the management system audited include: complaints, contract review, records storage, training, LIMS/IT, subtracting, preventive action, purchasing, service to the client, and control of non-conforming work.

It is the responsibility of the Director of Quality Assurance to plan and organize audits as required by the schedule and requested by management. These audits are carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

In addition to the scheduled internal audits, it may sometimes be necessary to conduct special audits as a follow-up to corrective actions, PT results, complaints, regulatory audits or alleged data integrity issues. These audits address specific issues.

The area audited, the audit findings, and corrective actions are recorded. Audits are reviewed after completion to assure that corrective actions were implemented and effective.

17.2 External Audits

It is the laboratory's policy to cooperate and assist with all external audits, whether performed by clients or an accrediting body. Management ensures that all areas of the laboratory are accessible to auditors as applicable and that appropriate personnel are available to assist in conducting the audit.

17.2.1 Confidential Business Information (CBI) Considerations

During on-site audits, on-site auditors may come into possession of information claimed as business confidential. A business confidentiality claim is defined as "a claim or allegation that business information is entitled to confidential treatment for

reasons of business confidentiality or a request for a determination that such information is entitled to such treatment." When information is claimed as business confidential, the laboratory must place on (or attach to) the information at the time it is submitted to the auditor, a cover sheet, stamped or typed legend or other suitable form of notice, employing language such as "trade secret", "proprietary" or "company confidential". Confidential portions of documents otherwise non-confidential must be clearly identified. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information.

17.3 Performance Audits

Performance audits may be Proficiency Test Samples, internal single-blind samples, double-blind samples through a provider or client, or anything that tests the performance of the analyst and method.

Proficiency Test Samples are discussed in Section 27 – "Quality Assurance for Environmental Testing".

17.4 System Audits

The Laboratory's management system is audited though annual management reviews. Refer to Section 18 – "Management Reviews" for further discussion of management reviews.

17.5 Handling Audit Findings

Internal or external audit findings are responded to within the time frame agreed to at the time of the audit. The response may include action plans that could not be completed within the response time frame. A completion date is established by management for each action item and included in the response.

The responsibility for developing and implementing corrective actions to findings is the responsibility of the Director of Quality Assurance and the appropriate department manager. Corrective actions are documented through the corrective action process described in Section 14 – "Corrective Actions".

Audit findings that cast doubt on the effectiveness of the laboratory operation to produce data of known and documented quality or that question the correctness or validity of sample results must be investigated. Corrective action procedures described in Section 14 – "Corrective Action" must be followed. Clients must be notified in writing if the investigation shows the laboratory results have been negatively affected and the clients' requirements have not been met. The client must be notified within three working days of the conclusion of the investigation and formulation of an appropriate corrective action**.** Laboratory management will ensure that this notification is carried out within the specified time frame.

All investigations that result in findings of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients. See Section 19 (Data Integrity Investigation) for additional procedures for handling inappropriate activity.

Section 18

MANAGEMENT REVIEWS
(TNI V1:M2 – Section 4.15)

Top management reviews the management system on an annual basis and maintains records of review findings and actions.

18.1 Management Review Topics

The following are reviewed to ensure their suitability and effectiveness:

- the suitability of policies and procedures;
- reports from managerial and supervisory personnel;
- the outcome of recent internal audits;
- corrective and preventive actions;
- assessments by external bodies;
- the results of proficiency tests;
- changes in the volume and type of the work;
- client feedback;
- complaints;
- recommendations for improvement;
- other relevant factors, such as quality control activities, resources, and staff training.

These items may be considered during strategic planning and regular management meetings.

18.2 Procedure

Findings and follow-up actions from management reviews are recorded. Management will determine appropriate completion dates for action items and ensure they are completed within the agreed upon time frame. Further information is documented in the SOP, QUALITY SYSTEM REVIEW PROCEDURE.

Section 19

DATA INTEGRITY INVESTIGATIONS
(TNI V1:M2 – Section 4.16)

In addition to covering data integrity investigations, this Section covers all topics related to ethics and data integrity policies, procedures and training.

PDC Laboratories, Inc. is committed to ensuring the integrity of its data and providing valid data of known and documented quality to its clients. The elements in PDC Laboratories, Inc.'s Ethics and Data Integrity program include:

- Documented data integrity procedures reviewed, signed and dated by senior staff.
- An Ethics and Data Integrity Agreement signed by all staff at time of employment and maintained by the Quality Assurance Department.
- New employee ethics orientation.
- Annual data integrity refresher training.
- Procedures for confidential reporting of alleged data integrity issues.
- An audit program that monitors data integrity (see Section 17 – "Audits") and procedures for handling data integrity investigations and client notifications.

19.1 Ethics and Data Integrity Procedures

The Ethics and Data Integrity Policy provides an overview of the program. Written procedures that are considered part of the Ethics and Data Integrity program include:

- Ethics and Data Integrity Policy (Appendix A)
- Chromatographic Peak Integration Procedures (SOP-GEN–ManInteg)
- Corrective action procedures (Section 14)
- Control of non-conforming environmental testing work (Section 12)
- Procedures for Data Integrity Investigations (Section 19.4)
- Data recall procedures (Sections 12.2 and 12.3)
- Data integrity training procedures (Section 19.2)
- New employee ethics orientation (third party training)

Senior Management reviews data integrity procedures yearly and updates these procedures as needed.

19.2 Training

Data integrity training is provided as a formal part of new employee orientation and a refresher is given annually for all employees. Employees are required to understand that any infractions of the laboratory data integrity procedures shall result in a detailed investigation that could lead to very serious consequences

including immediate termination, debarment or civil/criminal prosecution. Attendance for required training is monitored through a signature attendance sheet. Computer-based or on-line training is documented through read/understand forms signed, dated and returned to the QA Department upon completion.

An agenda is provided to each trainee prior to the training class. Data integrity training emphasizes the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient. The following topics and activities are covered:

- organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting;
- how and when to report data integrity issues;
- record keeping;
- training, including discussion regarding all data integrity procedures;
- data integrity training documentation;
- in-depth data monitoring and data integrity procedure documentation; and
- specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards.

When contracted technical or support personnel are used, the appropriate department manager is responsible for ensuring that they are trained to the laboratory's management system and data integrity procedures, competent to perform the assigned tasks, and appropriately supervised.

Topics covered are provided in writing and provided to all trainees.

19.3 Confidential Reporting of Ethics and Data Integrity Issues

PDC Laboratories, Inc. personnel who are aware of, or reasonably suspicious of, any unethical practice or misconduct occurring in the laboratory shall inform the appropriate department manager or director as soon as possible. However, if the employee is not comfortable with discussing the issue with the appropriate manager/director or if the manager/director does not satisfactorily address the concern, the Director of Quality Assurance should be contacted. If an individual desires complete confidentiality, a written statement should be sealed into an envelope and placed into the mailbox of the Director of Quality Assurance.

All questions or concerns will be taken seriously. The Director of Quality Assurance will assure confidentiality and a receptive environment in which to privately discuss a personal ethical dilemma with a staff member or observed unethical practices by other members of the staff. The Director of Quality Assurance will advise the Laboratory Vice President of a need for a detailed investigation

19.4 Investigations

The Director of Quality Assurance will conduct a confidential investigation using qualified technical and management personnel when warranted. The investigation may include interviews, data audits, internal method audits, and surveillance to determine any inappropriate practices. During the investigative process, if it becomes necessary to interview members of staff, a second member of the Senior Staff (Director) may be asked to attend for protection of both the interviewer and interviewee. The second person may also be a member of the Corporate Human Resources (HR) staff.

All data integrity incidents must be documented, including investigative findings, disciplinary actions and corrective actions. However, any disciplinary actions will become part of the employee's HR file, and thereby, be confidential to all except the employee, his supervisor and the HR department. All records of the investigation are kept strictly confidential and are maintained for a period of five years. Confidentiality of documentation is maintained by use of locked filing cabinets or desks and password protected electronic files. A summary of investigation results/disciplinary actions/corrective actions will be maintained for review to verify compliance with the TNI standard by the TNI assessor. However, the names of the individuals involved will be protected due to confidentiality guidelines issued by Human Resources. When an inappropriate practice has an impact on data integrity and reported values, the Laboratory Vice President will be informed and the Senior Project Manager or designee will initiate client contact and data recall if required.

PDC Laboratories, Inc. will not tolerate retaliation against anyone who in good faith asks a question or reports a concern. Any employee who retaliates against other employee for reporting a problem or raising an issue will be subject to discipline. This policy applies regardless of the ultimate outcome.

Section 20

PERSONNEL
(TNI V1:M2 – Section 5.2)

PDC Laboratories, Inc. employs competent personnel based on their education, training, experience and demonstrated skills as required by their position. The laboratory's organization chart can be found in Appendix B.

20.1 Overview

All personnel are responsible for complying with all quality and data integrity policies and procedures that are relevant to their area of responsibility.

All personnel who are involved in activities related to sample analysis, evaluation of results or who sign test reports, must demonstrate competence in their area of responsibility. Appropriate supervision is given to any personnel in training and the trainer is accountable for the quality of the trainees work. Personnel are qualified to perform the tasks they are responsible for based on education, training, experience and demonstrated skills as required for their area of responsibility.

The laboratory has established minimum requirements with respect to education, training and skills of laboratory staff for each general area of responsibility. These requirements are outlined in Table 20-1. Training needs are identified at the time of employment and when personnel are moved to a new position or new responsibilities are added to their job responsibilities. Ongoing training, as needed, is also provided to personnel in their current jobs. The effectiveness of the training must be evaluated before the training is considered complete.

Contracted personnel, when used, must meet the same competency standards and follow the same policies and procedures that laboratory employees must meet.

Table 20-1
Minimum Job Function Requirements

Area of Responsibility	Minimum Education	Minimum Experience
Microbiology	Four year degree in science field or equivalent experience or combination of education and experience	No experience necessary if degreed; minimum of one year experience in laboratory analysis if not degreed
Laboratory Systems Administrator	Two year degree or equivalent	One to two years experience; or equivalent combination of education and experience
QA/QC Coordinator	Four year degree in Chemistry, Biology or related scientific discipline	Two years experience in a chemistry laboratory in two or more departments; or equivalent combination of education and experience

Area of Responsibility	Minimum Education	Minimum Experience
Extraction Supervisor	Four year degree in Chemistry, Biology or related scientific discipline	Two years experience in a chemistry laboratory utilizing organic extraction methods; or equivalent combination of education and experience
Organics – Analyst	Four year degree in Chemistry, Biology or related scientific discipline	One to two years experience in a chemistry laboratory utilizing organic methods; or equivalent combination of education and experience
Organics - Technician	High School diploma or GED	No experience necessary
Metals Supervisor Wet Chemistry Supervisor	Four year degree in Chemistry, Biology or related scientific discipline	Two years experience in a chemistry laboratory utilizing inorganic methods; or equivalent combination of education and experience
Metals – Analyst Wet Chemistry - Analyst	Four year degree in Chemistry, Biology or related scientific discipline	One to two years experience in a chemistry laboratory utilizing inorganic methods; or equivalent combination of education and experience
Metals – Technician Wet Chemistry - Technician	High School diploma or GED	No experience necessary
Facility Support Supervisor	Two year degree or equivalent	Six months to one year of related experience and/or training; or equivalent combination of education and experience
Facility Support Technician	One year certificate or equivalent	Three to six months of related experience and/or training; or equivalent combination of education and experience
Sample Control Supervisor	High School diploma or GED	Two years supervisory experience
Sample Control Technician	High School diploma or GED	No experience necessary
Shipping Supervisor	High School diploma or GED	Two years supervisory experience
Shipping Technician	High School diploma or GED	No experience necessary
Courier Supervisor	High School diploma or GED	Two years supervisory experience
Courier	High School diploma or GED	Minimum of one year experience; possess a valid driver's license; able to pass IL MVR check (safe driving record)
Sampling Supervisor	Two year degree or field experience equivalent	No experience necessary; possess a valid driver's license; able to pass IL MVR check (safe

		driving record); lift 50 pounds
Area of Responsibility	**Minimum Education**	**Minimum Experience**
Sampling Technician	High School diploma or GED	No experience necessary; possess a valid driver's license; able to pass IL MVR check (safe driving record); lift 50 pounds
Project Manager Assistant	High School diploma or GED	No experience necessary
Administrative Assistant	High School diploma or GED	No experience necessary

20.2 Job Descriptions

Electronic versions of job descriptions for positions that manage, perform, or verify work affecting data quality are located in a shared network folder on a laboratory file server. An overview of senior management's responsibilities is included in Section 5 – "Management".

Job descriptions include the specific tasks, minimum education and qualifications, skills, and experience required for each position

20.3 Training

All personnel are appropriately trained and competent in their assigned tasks before they contribute to functions that can affect data quality. It is management's responsibility to assure personnel are trained. Training records are used to document management's approval of personnel competency. The date on which authorization and/or competence is confirmed is included.

Training records are maintained by senior management for each employee and include: documentation regarding specific training related to analyses performed, SOP review, source method review, MDL studies, initial demonstration of capability (IDOC) studies, ongoing demonstration of capability (DOC) studies and results of PT samples.

A separate file kept by the QA Department contains proof of education (diploma/transcripts), a signed Ethics and Data Integrity Agreement, training certificates/verifications, and summaries of departmental training records, IDOC and DOC studies, MDL studies and PT results.

20.3.1 Qualification of Trainers

To train another employee on a procedure, a trainer must have hands-on, working knowledge of the procedure and a complete and thorough understanding of the source method and SOP as evidenced by:

1. a training record sign-off for the procedure in their training file,
2. a "read/understood" sign-off for the supporting SOPs,

3. a “read/understood” sign-off for the source method, and
4. recent experience conducting the procedure including a current DOC.

The department manager may evaluate and approve individuals for test procedures based on relevant prior experience and education.

20.3.2 Training for New Staff

New staff members are given the following general laboratory orientation upon arrival:

1. Welcome – Orientation Overview and Agenda,
2. New Employee Payroll Documentation,
3. Anti-Harassment Acknowledgement,
4. Drug Free Workplace Acknowledgement,
5. Family Medical Leave Act Acknowledgement,
6. New Employee Network Sign on and Request Form,
7. Clock In/Out and Uniform & Equipment Forms, and
8. “Brief Lab Tour” – Restrooms and Break Room.

Additional “new employee” topics covered include:

1. Policy and Administration

    a. Employee Identification Register (signs printed and script name with initials)
    b. Ethics & Data Integrity Agreement (sign-off),
    c. Lab Security SOP,
    d. Instructions for Lab Security Systems,
    e. Lab Emergency Contact List,
    f. EEO/Veterans/Disability Form (fill-out),
    g. Funeral Leave Policy/Absence-Illness Policy,
    h. Paid Time Off Policy,
    i. Timesheet & Timecard Policy, Meal Break/Break, Lab Security, Passwords and Password Security Policy,
    j. Confidentiality,
    k. Electronic Communications Policy/Laboratory – New User Sign on Request,
    l. Lab coat and Dress Requirements,
    m. Recycling Program,
    n. Housekeeping Reminder Memo, and
    o. Contact the Health and Safety Officer (HSO) to schedule company physical (if applicable).

2. Provisions

    a. Lab coats,
    b. Locker Assignment, and
    c. Mailbox Assignment.

3. IT Orientation

    a. Computer/Internet Use Policy, and
    b. Computer User Logon Request

4. QA Orientation

    a. Quality Assurance Program – Overview,
    b. Quality Manual (sign-off), and
    c. Copy of applicant's resume and diploma/transcripts for QA employee file

The new employee orientation is documented on the Employee Orientation Checklist that outlines what was covered during the training.

20.3.3 Initial Training

The initial training for a new task contains the following steps:

1. All documentation involved with a new and unfamiliar task is read and understood by the trainee, including but not limited to SOP and source method documents.
2. Training is under direct supervision of a certified senior analyst. During the time the analyst is in training, the trainee may sign laboratory notebooks, logbooks, worksheets, etc. but they must be co-signed by the trainer.
3. The trainee must demonstrate competency in new tasks before they can perform independently, i.e., with a certified analyst not present at the time of testing. An IDOC must be performed to prove competency. Approval of competency is noted by the date and signature of the department manager on the training form.
4. Each step of the training process is documented. Records of certification are maintained by the department manager.
5. The documentation is kept in the employee's training record with a copy forwarded to the QA Department.

20.3.4 Ongoing Training

Staff members are given the following ongoing training, as applicable:

1. The employee attests, through signature, that they have read, understood, and agree to comply with the latest version of the Quality Manual and any SOPs, documented procedures or policies that the employee is responsible for following.
2. At least annually, the analyst demonstrates ongoing capability in each method they perform.
3. The employee attends in-house training relating to job function as applicable.
4. The employee participates in vendor training and workshops.
5. The employee attends refresher data integrity training.

6. The analyst attends health and safety training as required.
7. The staff member gains familiarization with administrative and personnel policies and procedures by HR or designate.

Training documentation is maintained in the employee's training record.

Section 21

ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS
(TNI V1:M2 – Section 5.3)

21.1 Environmental

The laboratory facility is designed and organized to facilitate testing of environmental samples. Environmental conditions are monitored to ensure that conditions do not invalidate results or adversely affect the required quality of any measurement.

The laboratory facilities are clean, have adequate temperature and humidity control, and have adequate lighting at the bench top. Since instrument performance can be affected by sources of heat and cold (e.g. direct sunlight), heating/cooling from air conditioner outlets, and drafts, and vibration, care is taken to ensure that effects from these various sources are minimized.

Instrument room temperatures are generally maintained between 50 to 95°F (10 - 35°C) as per instrument manufacturer's recommendations. Temperature fluctuations within a room are kept to a minimum. As the laboratory temperature increases, system reliability decreases. All electronic components generate heat while operating. This heat must be dissipated to the surrounding air for air for the components to continue to operate reliably.

The relative humidity of the operating environment is generally between 20% and 80%, with no condensation. Operating an instrument in an environment with very low humidity can cause the accumulation and discharge of static electricity, which can shorten the life of electronic components. Operating the system in an environment with high humidity can cause condensation, oxidation, and short circuits. It can also cause the accumulation of dust that can block filters on cooling fans.

The facility utilizes an uninterruptible power supply (UPS) with a back-up generator for critical equipment including computers, instrumentation, and ventilation. The UPS continually monitors incoming electrical power and removes the surges, spikes, sags, and other irregularities that are inherent in commercial utility power. The UPS system supplies clean, consistent power that sensitive electronic equipment requires for reliable operation. During brownouts, blackouts, and other power interruptions, batteries provide power to safeguard operation. A diesel laboratory reserve power generator augments the reserve batteries in the event of a sustained power failure.

If the laboratory environment is required to be controlled by a method or regulation, the adherence is recorded. The recording of the room temperature during TCLP extraction with a Min-Max thermometer documents that the required criteria are maintained.

Environmental tests are stopped when the environmental conditions jeopardize the results.

21.2 Work Areas

Work areas may include access and entryways to the laboratory, sample receipt area, sample storage area, sample process area, instrumental analysis area, chemical and waste storage area and data handling and storage area.

Access to, and use of, areas affecting the quality of the environmental tests is controlled by restriction of areas to authorized personnel only. See Section 21.4 below.

The laboratory work spaces are adequate for their use, and appropriately clean to support environmental testing and ensure an unencumbered work area. Laboratory area housekeeping direction falls primarily on the department managers and section supervisors. Detailed dusting and cleaning on laboratory benches, around instruments or equipment is to be performed by the employees responsible for their workspace. Facility support staff may assist in such cleaning, however, they are not to clean without the direct oversight of the employees or supervisory staff in that area.

Laboratory space is arranged to minimize cross-contamination between incompatible areas of the laboratory. The facility houses separate zoned laboratory areas that are served and separately controlled by a variable air volume (VAV) ventilation system. Control of the escape or entrance of air borne contaminants is a result of strategic control and operation of pressure controlled areas. This system includes two separate air handling and make-up air systems. In addition, two laboratories (Organic Volatiles Instrumentation and Total Organic Halides) have their own ventilation systems to minimize volatile air contamination. An assortment of fume hoods, including conventional hoods, slot hoods, canopy hoods, walk-in hoods, and a glove box are utilized to minimize contamination and to protect the staff. The Chemical Hygiene Officer monitors the hood efficiency in accordance with the Chemical Hygiene Plan.

A variety of large coolers, including walk-in style coolers, are available for the separate storage of samples from standards, standards from reagents, and to minimize cross contamination between different sample types. Select coolers are lockable as per client contract requirements with all coolers located in secure areas.

21.3 Floor Plan

A floor plan can be found in Appendix C.

21.4 Building Security

An electronic security system is utilized to control access to the facility. This system enables only authorized personnel to enter the facility through magnetic access keycard-controlled doors while automatically documenting the time of card

use. A security company provides 24 hour monitoring with a direct link to all doors and hallway motion detectors. Upon receipt of an alarm signal, security personnel call the laboratory facility. If the call goes unanswered, the service notifies authorities who respond in less than five minutes. The fire alarm is also tied into the security access monitoring for the purpose of monitoring the system and dispatching the fire department. In the event of a power failure, the alarm system is maintained by the UPS system.

The SOP, Laboratory Security, documents the measures that have been established to provide and ensure the physical security of PDC Laboratories, Inc.

A Visitor's Logbook is maintained for every visitor to sign in and out. Visitors must be accompanied by laboratory personnel when in secure areas. Visitors who need to go beyond the main reception area, the sample receiving area or the shipping area are required to sign a register log in order to gain entry to the rest of the facility. Visitors to PDC Laboratories, Inc. must wear a "Visitor" tag while in the facility. Visitors are the responsibility of the sponsoring laboratory employee. While in the facility, every effort must be made to ensure the safety of the visitor and the security of the facility. Sponsors must also take measures to protect the confidentiality of PDC Laboratories, Inc. and that of its clients. Sponsors must be conscientious to the workplace environment and preserve a productive work atmosphere for all other employees while they host a visitor.

Signs are used to designate secure or restricted areas.

Section 22

ENVIRONMENTAL METHODS AND METHOD VALIDATION
(TNI V1:M2 – Section 5.4 and Sections 1.4, 1.5 and 1.6 of Technical Modules TNI V1:M 3-7)

Methods and/or procedures are available for all activities associated with the analysis of the sample including preparation and testing. For purposes of this Section, "method" refers to both the sample preparation and determinative methods.

Before being put into use, a test method is confirmed by a demonstration of capability or method validation process.

All methods are published or documented. Deviations from the methods are allowed only if the deviation is documented, technically justified, authorized by management and accepted by the client

22.1 Method Selection

A reference method is a method issued by an organization generally recognized as competent to do so. (When ISO refers to a standard method, that term is equivalent to reference method.) When a laboratory is required to analyze a parameter by a specified method due to a regulatory requirement, the parameter/method combination is recognized as a reference method.

The laboratory will use methods that meet the needs of the client. Such methods will be based on the latest edition of the method unless it does not meet the needs of the client or an earlier version is mandated by the applicable regulatory authority.

The laboratory selects methods that are appropriate to the client needs. When the regulatory authority mandates or promulgates methods for a specific purpose, only those methods will be used.

If a method proposed by a client is considered to be inappropriate or out-of-date, the client is informed and the issue resolved before proceeding with analysis of any samples (see Section 7 – Review of Requests, Tenders and Contracts).

If a method is not specified by the client, an appropriate method will be selected based on client needs and available technology. The method selected should be capable of measuring the specific parameter of interest in the concentration range required and with the required precision and accuracy to meet the client's data quality objectives (DQOs). The client will be informed of the selected method and must approve its use before being used to report data.

All communications between the laboratory and the client are documented.

22.2 Laboratory-Developed Methods

If the laboratory develops a method, the process of designing and validating the method is carefully planned and documented. All personnel involved in the method design, development and implementation will be in constant communication during all stages of development.

The general procedure for methods development is outlined as follows:

Key Elements for Methods Development

Element 1: Identification of Scope and Application and Need

The key factor that a developer must establish before proceeding with a method development project is a clearly defined scope and application for the proposed method. Factors to be considered should include type of method (i.e., screening or quantitative), applicable target analytes, appropriate matrices, sensitivity, bias and precision, availability of equipment, and cost. A literature search is performed to determine whether similar methods already exist that can be modified to suit the new need.

Element 2: QC Requirements

When developing a method, the developer needs to identify the appropriate quality control procedures that must be performed to unequivocally demonstrate that the data generated by the method will meet the objectives defined in the scope and intended application(s).

Examples of QC elements include appropriate calibration criteria, tuning criteria, the need for replicate analyses, appropriate surrogates, blanks and spikes. QC criteria specific to the particular method should be well-documented and included in the QC section of the method as well as the method development report.

Element 3: Analytical Approach

A method must be practical, address a need and have the potential for general use in the environmental analytical community.

Element 4: Method/Instrument Sensitivity

The method sensitivity requirements for a proposed new method are influenced by several factors. These include the instrument detection limits, method quantitation limits, and any regulatory requirements for the proposed applications. Therefore, a method must exhibit analytical sensitivity appropriate for its intended application as delineated in the scope of the

method. Pertinent performance information to be included in the methods package should include the instrument or method detection and quantitation limits, i.e. the minimum mass of analyte which can be quantitated (or detected, in the case of screening methods), the instrument or method calibration for all target analytes and information as to whether the calibrations are linear or non-linear. At this stage in the methods development process, the analyst should demonstrate the appropriate analytical parameters and procedure on clean standards of known concentration.

Element 5: Method Optimization and Ruggedness Testing

After determining that the chosen analytical approach should work for its intended application with appropriate sensitivity, the method developer should begin to optimize the method. This task is accomplished using known standards.

The initial parameters should be chosen according to the analyst's best judgment. These are varied systematically to obtain the greatest response, least interference, greatest repeatability, etc. Developers must determine those variables which should not be changed without adversely affecting method performance. Potential operator-sensitive steps, e.g. color development time in colorimetric methods or other timed reactions, also need to be identified at this stage.

Element 6: Accuracy, Precision and Repeatability (Clean Matrix)

Accuracy, or in most cases method bias, is defined as nearness to the true value. Precision is defined as the dispersion of results around the mean value. Repeatability (or long-term precision) is defined as the ability to reproduce a measurement from one week to the next.

Bias is measured by determination of % recovery of target analytes spiked into the matrix of concern. An acceptable spike recovery range for most method development applications is from 80% to 120%. Precision is measured as relative % difference of target analyte concentration(s) between duplicates or duplicate spikes and should be <20%. Repeatability, measured as long-term precision (e.g. weekly), should not vary by more than 15% when the instrument is calibrated using comparable standards on different days.

These are key method performance factors which determine how a method can be used in real world situations. The initial determination of bias, precision and repeatability should be made in a spiked clean matrix which is similar to a real environmental matrix but free from interferences, e.g., reagent water, sand or soil. These values should be obtained using multiple replicates at both high and low spike concentrations.

Element 7: Effect of Interferences

The determination of method interferences, both positive and negative is a key factor in method development. It is a critical element in methods development to determine the effects of potential analytical interferences and to develop techniques to minimize or eliminate these interferences. In chromatographic methods, interferences include co-eluting peaks and/or analyte degradation due to interaction with the injector port, transfer line or columns. In spectroscopic methods, interferences can result from overlapping spectral lines causing either positive or negative signal enhancement.

Method interferences should be determined in a spiked clean matrix. Developers should determine the effects of interferences in a potential new method between target analytes and other compounds reasonably expected to be present in waste matrices.

False negative rates, i.e., the percentage that a method generates a negative result when the sample contains the target analyte at or above the action level and false positive rates, i.e., the percentage that a method generates a positive result when the sample contains the target analytes below the action level, are critical factors which will determine the utility of a potential method for its intended application.

Documentation of interferences should include any co-elution of or with target analytes, any enhancements or suppression of target analyte signals caused by interferences, any necessary or optional cleanup procedures to minimize the effect of interferences, and any matrix-specific difficulties.

Element 8: Matrix Suitability

The previous elements of the methods development process involved the use of either known standards or target analytes spiked into clean matrices, designed to indicate potential method performance in real world matrices. Once the potential new method has passed all of the preliminary tests, it is now ready for the most important demonstration in the entire methods development process, i.e. how it will perform in real world matrices for which it is intended to be used.

The method should be suitable for a variety of matrix types. Matrix types refer to different matrices within a particular medium, e.g. water and soil. Water matrices include groundwater, TCLP leachate and wastewater while appropriate soil matrices include sand, loam and clay. The method should perform adequately in a variety of spiked matrices and then in a variety of well-characterized natural samples. Performance data including matrix, precision bias, quantitation limits, and any other pertinent data should be included in appropriate tables.

Element 9: Quantitation and Detection Limits

The developer should develop estimated method quantitation limits (EQL) and method detection limits (MDL) for the analytes of concern in the matrices of concern.

Method detection and quantitation limits for a determinative method are usually based on a specific sample size and a specific preparation scheme. The limits determined in clean matrices indicate the limits of acceptable performance for the method. Matrix effects may affect the achievable quantitation limits on real world samples. However, the method quantitation limits for the target analytes in the target matrices must meet the analytical requirements of the intended application, as defined in the scope of the method. Quantitation limits for the target analytes in representative matrices should be included in summary tables in the methods, while the rationale for and details of the MDL and EQL concentrations should be included in the supporting documentation.

Element 10: Laboratory Reproducibility (Multiple Operators/Laboratories)

The final stage in the method development process is the determination of laboratory reproducibility. Reproducibility means that multiple operators and multiple laboratories should be able to obtain comparable performance data on split samples using the method. Since all of the previous elements involved single operators or single laboratories, it is necessary to demonstrate that satisfactory method performance is not limited to the individual operator or laboratory that developed the method.

The minimum number of laboratories that are needed to participate in a multi-laboratory method validation is three, with preferably more.

In order to minimize the number of variables involved in method validation, the developer needs to follow a few simple guidelines to demonstrate appropriate multi-laboratory method performance. When validating a sample preparation method, the participating laboratories should only perform the sample preparation procedure. The collected samples should then be sent to one laboratory for analysis. The analysis should be done by a single operator on a single instrument in a single batch to minimize variability inherent to the determinative method. Conversely, if a determinative method is to be validated, the developer should have a single operator perform all of the sample preparation operations in order to minimize operator and laboratory variability inherent to sample preparative procedures. The sample extracts should then be split and sent to the laboratories participating in the validation study for the analytical determination.

Element 11: Document Submission and Workgroup Evaluation

When the method project is completed, the developer must assemble a package of documents describing the project and submit to the TNI Accreditation Body for review/evaluation and for accreditation. This documentation package should include 1) a cover letter requesting the addition of new parameters by the new method to the current parameter list; 2) a copy of the appropriate application page with the requested analytes checked (matrix specific); 3) a copy of the final, signed Standard Operating Procedure (SOP) of the method; 4) a copy of the requisite Method Detection Limit (MDL) study with supporting documentation (standards); 5) a copy of the Initial Demonstration of Capability (IDOC) with supporting documentation (standards); and copies of the results of two Proficiency Testing samples (PTs) analyzed at least 15 days apart. The package may be either hard copy or electronic depending on which Accreditation Body receives the request.

Additional supporting documentation that may be requested may include a data package containing the raw and summarized single laboratory and multi-laboratory data, any specific equipment diagrams and chromatograms, spectra, etc. pertinent to the demonstration of appropriate performance for the intended application of the method, copies of any references listed in the method and any method-specific quality control criteria.

22.3 Method Validation

Validation is the confirmation, by examination and objective evidence, that the particular requirements for a specific intended use are fulfilled.

At a minimum, reference methods are validated by performing an initial demonstration of capability. Additional requirements are discussed for each technology.

All methods that are not reference methods are validated before use. The validation is designed so that the laboratory can demonstrate that the method is appropriate for its intended use. All records (e.g., planning, method procedure, raw data and data analysis) shall be retained while the method is in use. Based on the validation process, the laboratory will make a statement in the Scope and Application section of the SOP of the intended use requirements and whether or not the validated method meets the use requirements.

Method validation and Demonstration of Capability procedures can be found in Appendix G – Chemistry.

22.4 Estimation of Analytical Uncertainty

Analytical Uncertainty: A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis.

When requested, the laboratory will provide an estimate of the analytical uncertainty as determined by quality control element measurement data as

referenced in the current revision of SOP #900_QA-EstMeasUncert, Estimation of Measurement Uncertainty.

22.5 Control of Data

To ensure that data are protected from inadvertent changes or unintentional destruction, the laboratory uses procedures to check calculations and data transfers (both manual and automated).

22.5.1 Computer and Electronic Data Requirements

The laboratory assures that computers, user-developed computer software, automated equipment, or microprocessors used for the acquisition, processing, recording, reporting, storage, or retrieval of environmental test data are:

- documented in sufficient detail and validated as being adequate for use;
- protected for integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;
- maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of environmental test data; and
- held secure including the prevention of unauthorized access to, and the unauthorized amendment of, computer records. Different Users of the Element DataSystem® have different permission settings, which allow access to certain areas of the LIMS. Permissions may be set as **View**, **Edit**, or **No Access**. With **View** permission, a User can access a program area, but they will not be able to make any changes to data. With **Edit** permission, a User will be able to access a program area and be able to make changes to the data. If a User's permissions are set to **No Access** for a given program area, that User will not be able to View or Edit that program area; the menu items in those program areas will be greyed-out. Data archive security is addressed in Section 16 – "Control of Records" and building security is addressed in Section 21- "Accommodations and Environmental Conditions".

Commercial off-the shelf software in general use within their designed application range may be considered to be sufficiently validated.

The laboratory uses spreadsheets to calculate final results from the raw data for selected methods such as BOD. To ensure that the spreadsheet formulae are correct, the laboratory tests each set of cells used for input of the data as well as cells used for calculations by comparing the results of the spreadsheet with manually calculated data. The results of this verification are noted by the IT Department. A
The data stored in the Element DataSystem® is backed-up daily off-site (cloud storage). All other data system back-ups are done in-house daily. Access to

protected records is limited to the Corporate IT Manager and to the Laboratory Systems Administrator to prevent unauthorized access or amendment.

22.5.2 Data Reduction

The Element DataSystem® calculates final results from raw data using appropriate "interpreter" programs to provide the results in a reportable format. The test methods provide required concentration units, calculation formulae and any other information used to obtain final analytical results.

The laboratory has manual integration procedures that must be followed when integrating peaks during data reduction as referenced in the current revision of SOP-GEN-ManInteg, Chromatographic Peak Integration Procedures.

The use of significant figures has been set in each individual method during the set-up of Element DataSystem® by the respective department managers and adjusted as needed for various reporting requirements.

All raw data must be retained as stated in the current revision of SOP-GEN-HrdcpyRecStrge, Hardcopy Record Storage, Retrieval and Disposal and it is maintained as described in Section 16 – "Control of Records".

22.5.3 Data Review Procedures

Data review procedures are located in Section 27.4 – "Data Review".

Section 23

CALIBRATION REQUIREMENTS
(TNI V1:M2 – Sect 5.5 and Section 1.7 of Technical Modules TNI V1:M 3-7)

The Microbiology Department is certified through the Illinois Department of Public Health (IDPH) and as such follows 77 Illinois Administrative Code 465,Title 77: Public Health, Chapter 1, Subchapter d, Part 465: Certification and Operation of Environmental Laboratories. References to the Microbiology Department will be set apart in Italics within brackets.

23.1 General Equipment Requirements

The laboratory provides all the necessary equipment required for the correct performance of the scope of environmental testing performed by the laboratory.

All equipment and software used for testing and sampling are capable of achieving the accuracy required for complying with the specifications of the environmental test methods as specified in the laboratory SOPs.

Equipment is operated only by authorized and trained personnel (see Section 20 – "Personnel"*)*.

The laboratory has procedures for the use, maintenance, handling, storage, and transportation of equipment which are readily available to laboratory personnel. Manuals provided by the manufacturers of the equipment provide information on use, maintenance, handling and storage of the equipment. The laboratory maintains a list of major equipment in Table 23-1 that includes information on instrument location. Table 23-2 provides summaries of general planned equipment maintenance. These procedures ensure proper functioning of the equipment and prevent contamination or deterioration. Maintenance of specific instruments may be found in laboratory SOPs or referenced in the specific manufacturers' manuals.

All equipment is calibrated or verified before being placed in use to ensure that it meets laboratory specifications and relevant standard specifications. Depending on the type of equipment or instrument, calibration documentation may be kept with the instrument in the equipment work area or included with data packages.

[The Microbiology Department follows the manufacturer's guidelines for calibration and documents relevant specifications for equipment (e.g. temperature, pH) in the work area or in Microbiology QC notebooks in Room 176.]

Test equipment, including hardware and software, are safeguarded from adjustments that would invalidate the test result measurements by limiting access to the equipment and using password protection where possible (see Section 22.5 – "Control of Data"*)*.

Equipment that has been subject to overloading, mishandling, given suspect results, or shown to be defective or outside specifications is taken out of service. The equipment is isolated to prevent its use or clearly labeled as being out of service until it has been shown to function properly. If it is shown that previous tests are affected, then procedures for nonconforming work are followed and results are documented (see Section 12 – "Control of Nonconforming Environmental Testing Work" and Section 14 – "Corrective Action").

When equipment is needed for a test that is outside of permanent control of the laboratory, the lab ensures the equipment meets the requirements of this manual prior to its use by inspecting or otherwise testing it.

[The Microbiology Department does not use equipment that is outside of the permanent control of the laboratory.]

Each item of equipment and software used for testing and significant to the results is uniquely identified. Records of equipment and software are maintained. This information includes the following:

a. identity of the equipment and its software;
b. manufacturer's name, type identification, serial number or other unique identifier;
c. checks that equipment complies with specifications of applicable tests;
d. current location;
e. manufacturer's instructions, if available, or a reference to their location;
f. dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
g. maintenance plan where appropriate, and maintenance carried out to date; documentation on all routine and non-routine maintenance activities and reference material verifications; and
h. any damage, malfunction, modification or repair to the equipment.

Table 23-1 Laboratory Equipment (May 2012)			
Name (Quantity)	**Room**	**Brand / Model / Configuration**	**Unique Identifier**
ICP-MS	113	Perkin Elmer/ELAN-6000	ICPMS 6000
ICP-MS	113	Perkin Elmer/DRC-e	ICPMS DRC
ICP	112	Perkin Elmer/Optima 7300 Dual View	ICP 7300
Mercury Analyzer	112	Leeman Hydra AA Automated	HG AA
Microwave Digester	169	CEM Mars	MARS
Microwave Digester	169	CEM Mars	MARS 5
Hot Blocks (2)	169	Environmental Express	---
Turbidity meter	112	HACH	T-1
GC	123	HP 5890/dual ECDs	GC, GE, GF, GG
GC	123	Agilent 6890/dual ECDs	GD, GI, GR
GC	123	Agilent 6890/dual NP detectors	GH
GC	123	HP 5890/FID	GO
GC	123	HP 5890/dual FIDs	GB
HRGC-HRMS	111	Agilent 7890/Waters Autospec Premier	ML
Chiller	133	Thermo Scientific Neslab HX-500	---
GC-MS	123	HP 5890/5971 systems	ME
GC-MS	130	HP 5890/5971 systems	MG, MD
GC-MS	123	HP 5890/5972 systems	MA, MC
GC-MS	130	HP 5890/5972 systems	MB
GC-MS	123	Agilent 6890/5973 system	MK
GC-MS	123	Agilent 7890/5975 systems	MJ
GC-MS	130	Agilent 7890/5975 systems	MH, MI
GC-MS	123	Thermo ISQ GC/MS system	MF
HPLC (3)	123	Agilent 1100 systems	LA, LD, LF
		Diode Array Detectors (3)	
		Pickering Post Column Derivatization (2)	
		Fluorescence Detectors (3)	
HPLC (1)	123	HP 1090 system	LB
		Fluorescence Detector (1)	
		Diode Array Detector (1)	
		Post Column Derivatization (1)	
HPLC (1)	123	Shimadzu LC-10AS system	LC
		SPD-10AV UV Detector (1)	
Concentrators (2)	130	Tekmar 3000	T2, T5
Concentrators (3)	130	EST Encon Concentrators	T7, T8, T9

Table 23-1 Laboratory Equipment (May 2012)			
Name (Quantity)	**Room**	**Brand / Model / Configuration**	**Unique Identifier**
Autosamplers (2)	130	EST Centurion	P9, P10
Autosamplers (2)	130	EST Centurion	P11, P12
Autosamplers (1)	130	Varian Archon	P4
Sonic Disruptors(3)	165	Misonix XL-2020 Dual Head	A, B, C
TurboVaps (4)	165	Biotage TurboVap II Workstations	TV1 – TV4
Nitrogen Evaporator (3)	165	Organomotion N-EVAP Model 111	2, 3, 4
Nitrogen Evaporator	174	Organomotion N-EVAP Model 111	1
Solvent Evaporator (2)	165	Organomotion OA-SYS	B, C
Solvent Evaporator	174	Organomotion OA-SYS	A
SPE Manifolds (2)	165	Supelco Visiprep 12 station manifold	---
SPE Manifold	174	Supelco Visiprep 12 station manifold	---
Vacuum Manifold	174	Supelco Visiprep DL 3 position Dioxin	---
Soxhlet units (6)	174	Liquid-Liquid Soxhlet extraction units	---
SPE extractors (4)	165	Horizon SPEDEX 4790	1, 2, 3, 4
Flatbed Orbital Shaker	165	VWR DS-500	---
Vacuum Manifold	174	Three position Dioxin vacuum manifold	---
Sonic Disruptor	165	Single head	---
Wrist Action Shaker (2)	165	Burrell Model 75	---
3D Floor Shaker	165	Glas-Col	---
Vacuum Pump	165	Vacuubrand ME 1C	---
Vacuum Pump	165	Vacuubrand ME 2	---
Chiller	165	FisherSci	---
Oven	165	S/P TempCon	---
Hot Block	165	Fisher IsoTemp	---
Vacuum Pump	174	KNF	---
Organic HX Analyzer	114	Mitsubishi Sigma 10	TOX-01
Organic HX Analyzer	114	Mitsubishi AOX-200	AOX-1
Preparation Stations (2)	114	MCI TOX 10A	---
Preparation Stations (2)	114	MCI TXA-02	---
Centrifuge	114	Fisher Model 228	---
Vortex Mixer	114	Thermolyne	---
Ion analyzer/pH/Cond	160	Fisher Accumet 50 Dual Electrode	PROBE-01
Flashpoint Tester	160	Fisher Tag Closed Cup	---
Flashpoint tester	160	Koehler Open Cup	---
CN Distillation (3)	160	MIDI-STIL Cyanide Distillation Systems	---
TKN Digestion (2)	160	Buchi TKN Digestion System	D1
TKN Distiller	160	Buchi TKN Distillation System	D2
Ion Chromatograph	146	Dionex ICS-5000	IC-04

Table 23-1 Laboratory Equipment (May 2012)			
Name (Quantity)	**Room**	**Brand/Model/Configuration**	**Unique Identifier**
Ion Chromatograph (2)	146	Dionex ICS-1000	IC-02, IC-03
COD Reactors (3)	160	HACH	CR 1 through 4
G & O Extractor	160	Horizon SPEDEX 3000XL	GO1
G & O Extractor	160	Horizon SPEDEX 3000XL	GO2
Auto Analyzer	114	Lachat QuickChem FIA + 8000	LACH-1
Auto Analyzer	151	Lachat QuickChem FIA + 8000	LACH-2
Ion Analyzer	160	Orion EA 920	---
Ion analyzer/pH/Cond	160	Accumet 25	---
TOC Analyzer	146	OI Analytical 1030/1088 Autosampler	TOC-01
Spectrophotometer	160	Spectronic Unicam Genesys 20	Genesys 20
Spectrophotometer	160	Spectronic Unicam Genesys 10	Genesys 10
DO (BOD) Meter	160	YSI Model 5000	DO-01
DO (BOD) Meter	160	YSI Model 5100	DO-02
Muffle furnace	160	Thermolyne	6018
Auto-Titrator	160	Metrohm	---
Incubator A	176	VWR Scientific 1545	700996
Incubator B	176	VWR Scientific 1545	100104
Incubator C	176	Fisher 307C	1519060787444
Incubator D	160	Blue M 200A	IN-1-6520
Spore Incubator	176	Blue M SW-11TA	S3-587
Hallway Incubator	by 166	Napco Model 6200	1-87-2237-22
Back Fecal Water Bath	160	Precision 51221033	603121288
Front Fecal Water Bath	160	Precision 51221033	604101191
SPC Tempering Bath	176	Napco Model 220	MSR-3
Refrigerator	176	True T-23	716646
pH Meter	176	Fisher Accumet Basic	6356
Conductivity Meter	160	EC 2052	209002
Vacuum Pump 1	176	GE 5KH33GN293KX	J07J230283
Vacuum Pump 2	176	GE 5KH33GN293KX	F07J010064
Vacuum Pump 3	160	GE 5KH33DN16JX	XYJ260109
Vacuum Pump 4	134	GE 5KH33DN16AX	JXD
Quantitray Sealer	160	Idexx 2X 89-10894-04	05623-08-022
Autoclave 1	166	Market Forge STME	68502
Autoclave 2	166	Market Forge STME	C-0913
Lab Blender	160	Waring 1120	2
Stir Plate	176	Fisher 120MR	106
Hot Plate	176	Corning C6R	30296
Balance	160	Mettler PM200	101

Table 23-1 Laboratory Equipment (May 2012)			
Name (Quantity)	**Room**	**Brand / Model / Configuration**	**Unique Identifier**
Balance	176	Oahus EA000D	102
Balance	169	Mettler PM480	104
Balance	167	Mettler PB3002	105
Balance	160	Mettler AG204	107
Balance	160	Mettler AG204	110
Balance	129	Mettler PM600	112
Balance	122	Mettler AG245	114
Balance	165	Mettler BB300	115
Balance	160	Mettler B601	119
Balance	167	Mettler AE160	120
Balance	160	Mettler AE160	122
Balance	160	Mettler XS204	123
Balance	167	Mettler XS2002S	124
Balance	160	Denver Instruments MXX-5001	125
Balance	135	Denver Instruments MXX-601	126
Class 1 Weight	167	20mg -100 g Polished Kit	Metals-002
Class 1 Weight	129	100 mg – 100 g Polished Kit	S1986
Class 1 Weight	176	2000g Polished Weight	300048.1
Class 1 Weight	176	2000g Polished Weight	84200.1
Class 1 Weight	160	50 mg – 50 g Weight Set	94-0585278
Class 1 Weight	160	2mg, 50g Polished Kit	95082195
NIST Thermometer	124	VWR Scientific	1 (B46387)
NIST Thermometer	124	Ertco	2 (1692)
NIST Thermometer	124	Ertco	3 (1675)
NIST Thermometer	124	Ertco	4A (02103)
NIST Thermometer	124	VWR Scientific	5 (B46465)

23.2 Support Equipment

Support Equipment includes, but is not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices, volumetric dispensing devices, and thermal/pressure sample preparation devices.

All support equipment is maintained in proper working order. Records are kept for all repair and maintenance activities, including service calls.

[Repair/maintenance for the Microbiology Department is recorded in the Maintenance logbook in Room 176]

All raw data records are retained to document equipment performance. These records include logbooks, data sheets, or equipment computer files.

23.2.1 Support Equipment Maintenance

Regular maintenance of support equipment, such as balances and fume hoods is conducted at least annually.

Maintenance on other support equipment, such as ovens, refrigerators, and thermometers is conducted on an as needed basis.

Records of maintenance to support equipment are documented in Instrument Maintenance Logs. Each piece of support equipment does not necessarily have its *own* logbook but must be documented. Maintenance logbooks may be shared with equipment that is housed in the same laboratory area. Table 23-2 includes a general summary of support equipment maintenance that encompasses organics, inorganics, and microbiology. There may be variation between the departments depending upon the equipment and its intended use and the requirements of the accrediting or certifying body.

[Maintenance information for the Microbiological Department is kept in the "Bacteriology Equipment Maintenance Log"]

Table 23-2 Summary of Support Equipment Calibration And Maintenance

Instrument	Activity	Frequency	Documentation
Balance	1. Clean 2. Check alignment 3. Check with standards 4. Service Contract	1. Before use 2. Before use 3. Daily 4. Annually	Worksheet/log book Post annual service date on balance
ASTM Class 1 Weights	1. Only use for the intended purpose 2. Use plastic forceps to handle 3. Keep in case 4. Re-calibrate	Every 5 years if weight is used only to check working standard weights which are then used for the daily checks.	Keep certificate
Working Standard Weights	Used to check balances before their use.	Daily; Before use	Worksheet / logbook
NIST Traceable Thermometer	Used to calibrate working thermometers; accuracy determined by A2LA-accredited weights and measurement laboratory	Annually	Keep certificate
Thermometers: 1. Glass and electronic 2. Infrared	Check at the temperature used, against a reference NIST certified thermometer Check electronic against new certified electronic thermometer as reference	1. Annually for glass and electronic types 2. Quarterly for IR and dial type	Calibration factor and date of calibration on thermometer and worksheet/log book

Table 23-2 Summary of Support Equipment Calibration And Maintenance			
Instrument	**Activity**	**Frequency**	**Documentation**
pH electrometers	Calibration: 1. pH buffer aliquot are used only once 2. Buffers used for calibration will bracket the pH of the media, reagent, or sample tested. 3. *[Slope between 95-105%]*	Before use *[Daily]* *[Daily]* *[Daily]*	Worksheet/log book
pH probe	Maintenance: Use manufacturer's specifications *[Probe replaced]*	As needed *[Annually or as needed]*	Worksheet/log book
photometer	1. Keep cells clean 2. Service contract. Check wavelength settings with color standards	Annually	Post service date on photometer
Automatic or digital type pipettes	Calibrate for accuracy and precision using reagent water and analytical balance	Weekly	Worksheet/logbook
Refrigerators, Freezers, and BOD incubators	1. Thermometers are immersed in liquid to the appropriate immersion line 2. The thermometers are graduated in increments of 1°C or less	Temperatures are recorded each day in use	Worksheet/log book
Autoclave	1. Use a maximum-temperature-registering thermometer or a continuous recording device. 2. Use spore strips or ampoules. 3. In house maintenance of autoclave or service contract. 4. Hot air ovens must maintain a stable temperature of 170°C - 180°C for at least two hours	1. Each cycle 2. One sterilizing cycle per month. 3. As needed ; at least once per year	Worksheet/log book

Table 23-2 Summary of Support Equipment Calibration And Maintenance			
Instrument	**Activity**	**Frequency**	**Documentation**
Microbiological incubators, and water baths	1. Thermometers in each unit are immersed in liquid to the appropriate immersion line 2. The thermometers will be graduated in increments of 0.5°C (0.2°C increments for tests which are incubated at 44.5°C) or less	Temperature of water baths will be recorded once a day for each day of use and for incubators twice a day for each day in use	Worksheet/log book
DO electrometer	Calibrate as specified in SOP	Before use	Worksheet/log book
DO probe	Maintenance as specified by manufacturer	As needed	Worksheet/log book
[Conductivity meter]	*[Calibrated with traceable low level standard]*	*[Each use]*	*[Worksheet]*
[UV lamp]	*[Bulbs cleaned with ethanol]* *[Output tested to be not less than 70% of original output]*	*[Monthly]* *[Monthly]*	*[Worksheet]* *[Worksheet]*
[Quantitray Sealer]	*[Checked with dye for leaks to ensure good seal]*	*[Monthly]*	*[Worksheet]*

23.2.2 Support Equipment Calibration

All support equipment is calibrated or verified annually over the entire range of use using NIST traceable references where available. The results the calibration of support equipment is within specifications or (1) the equipment is removed from service until repaired, or (2) records are maintained of correction factors to correct all measurements. If correction factors are used this information is clearly marked on or near the equipment.

Support equipment such as balances, ovens, refrigerators, freezers, and water baths are verified with a NIST traceable reference if available, each day prior to use, to ensure operation is within the expected range for the application for which the equipment is to be used.

Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) are checked for accuracy on a quarterly basis.

Table 23-3A Calibration Acceptance Criteria for Support Equipment				
Equipment	**Type of Calibration / Number of Standards**	**Frequency**	**Acceptance Limits**	**Corrective Action**
Analytical Balance	Accuracy determined using A2LA-accredited NIST weights. Minimum of 2 or 3 standards bracketing the weight of interest depending on use. Inspected and calibrated by A2LA accredited person annually.	Daily or before use	± 0.2% or as stated by manufacturer	Clean, check level, insure lack of drafts, and that unit is warmed up, recheck. If fails, call service.
Thermometer	Against NIST-traceable thermometer	Yearly at appropriate temperature range for intended use	± 2.0°C	Replace
Electronic Thermometer	Against new certified electronic thermometer	Yearly	± 1.5°C	Replace
InfraRed Temperature Guns	Against NIST-traceable thermometer	Quarterly at appropriate temperature range for intended use	± 1.5°C	Repair/replace
Volumetric Dispensing Devices (Eppendorf ® pipette, automatic dilutor or dispensing devices)	One delivery by weight. Using DI water, dispense into tared vessel. Record weight with device ID number.	Weekly	± 2% (10 – 100 ul) ± 5% (101 – 1000 ul)	Adjust. Replace.

Table 23-3B Calibration Acceptance Criteria for Microbiological Support Equipment				
Equipment	**Type of Calibration / Number of Standards**	**Frequency**	**Acceptance Limits**	**Corrective Action**
Analytical Balance	Accuracy determined using A2LA-accredited NIST weights. Minimum of 3 standards bracketing the weight of interest. Inspected and calibrated by A2LA accredited person	Daily Annually	Balance used to weigh more than 2 g must detect 100 mg at a 150 g load Balance used to weigh less than 2 g must be sensitive to 1 mg at a 10 g load	Clean, check level, insure lack of drafts, and recheck. Have serviced if still unacceptable
Thermometer	Against NIST-traceable thermometer	Annually at appropriate temperature range for intended use	± 1.0°C	Replace
MRT Thermometers	Against NIST-traceable thermometer	Annually at appropriate temperature range for intended use	± 1.0°C	Replace
pH Meter	Calibrated using at least two standards	Daily	Slope (95-105%)	Replace
InfraRed Temperature Guns	Against NIST-traceable thermometer	Yearly at appropriate temperature range for intended use	± 1.5°C	Repair/replace
Volumetric Dispensing Devices (Eppendorf ® pipette, automatic dilutor or dispensing devices)	One delivery by weight. Using DI water, dispense into tared vessel. Record weight with device ID number.	Weekly	± 2% (10 – 100 ul) ± 5% (101 – 1000 ul)	Adjust. Replace.

Table 23-4 Acceptance Criteria for Microbiological Support Equipment		
Equipment Identification	**Use**	**Acceptance Criteria**
Incubator A	General microbiological use	35.0°C ± 0.5°C
Incubator B	Heterotrophic Plate Count	35.0°C ± 0.5°C

Table 23-4 Acceptance Criteria for Microbiological Support Equipment		
Equipment Identification	**Use**	**Acceptance Criteria**
Incubator C	Routine Colilert samples	35.0°C ± 0.5°C
Incubator D	Sludges/waste water Quantitrays	35.0°C ± 0.5°C
Spore Incubator	Spore ampules	56-60°C
Hall incubator	Sludge overflow	45.5°C ± 0.2°C
Back Fecal Water bath	Sludges/ waste water MFs	45.5°C ± 0.2°C
Front Fecal Water bath	Pre-warming Colilert samples	45.5°C ± 0.2°C
SPC Tempering Water bath	Melting agar	45°C ± 1°C
Refrigerator	Reagent/ media/sample storage	0 to 5°C
Autoclave	Sterilization	122°C± 1°C

23.3 Analytical Equipment

23.3.1 Maintenance for Analytical Equipment

All equipment is properly maintained, inspected, and cleaned.

Maintenance of analytical instruments and other equipment may include regularly scheduled preventive maintenance or maintenance on an as-needed basis. Instrument malfunction is documented in the specific instrument maintenance logbooks [Bacteriology Equipment Maintenance Log] which become part of the laboratory's permanent records. A description of what was done to repair the malfunction and proof of return to control are also documented in the log. When the equipment is repaired by an outside source, a copy of the repair bill is placed in the logbook to explain what was done. Proof of return to control can be a statement that a QC sample was run and that it passed acceptance criteria.

Table 23-5A Analytical Equipment Maintenance		
Instrument	**Procedure**	**Frequency**
Leeman Mercury Analyzer	Check tubing for wear Fill rinse tank with 10% HCl Insert clean drying tube filled with Magnesium Perchlorate Fill reductant bottle with 10% Stannous Chloride	Daily Daily As required Daily
ICP ICP/MS	Check pump tubing/replace Check liquid argon supply Check fluid level in waste container	Daily Daily Daily

Table 23-5A Analytical Equipment Maintenance		
Instrument	**Procedure**	**Frequency**
ICP ICP/MS (cont.)	Check filters Clean or replace filters Check torch Check sample spray chamber for debris Clean nebulizer	Monthly As required Daily As required As required
UV-Vis Spectrophotometer	Clean ambient flow cell Precision check/alignment of flow cell Wavelength verification check	As required As required Semi-annually
Auto Analyzers	Clean sampler Check all tubing Clean inside of colorimeter Clean pump well and pump rollers Clean optics and cells	Daily Daily As required As required As required
IR Spectrophotometer	Clean cell Check/adjust cell alignment	Annually As required
GC/MS	Ion gauge tube degassing Pump oil-level check Pump oil changing Analyzer bake-out Analyzer cleaning Resolution adjustment	As required As required Annually As required As required` As required
Gas Chromatograph	Compare standard response to previous day or since last initial calibration Check carrier gas flow rate in column Check temp. of detector, inlet, column oven Septum replacement Glass wool replacement Check for loose/fray wires and insulation Bake injector/column Change/remove sections of guard column Replace connectors/liners Change/replace column(s)	As required As required As required As required As required As required As required As required As required As required
Electron Capture Detector (ECD)	Detector wipe test (Ni-63) Detector cleaning	Semi-annually As required
Flame Ionization Detector (FID)	Detector cleaning	As required
Hall 700A Detector Hall 1000 Detector	Electrolyte change Reactor tube/teflon connecting tube change Clean detector cell	As required by noise As required As required
HPLC	Change guard columns Change lamps	As required As required

Table 23-5A Analytical Equipment Maintenance		
Instrument	**Procedure**	**Frequency**
HPLC (cont.)	Change pump seals Replace tubing Change fuses in power supply Filter all samples and solvents Change autosampler rotor/stator	As required As required As required As required As required
Balances	Class "1" traceable weight check Clean pan and check if level Field service	Daily, when used Daily At least annually
Conductivity Meter	0.01 M KCl calibration Conductivity cell cleaning	Daily As required
Turbidimeter	Check light bulb	Daily, when used
Deionized/Distilled Water	Check resistivity Check deionizer light (if present) Monitor for VOA's System cleaning Replace cartridge & large mixed bed resins	Daily, when used Daily, when used Daily, when used As required As required
Drying Ovens	Temperature monitoring Temperature adjustments	Daily As required
Refrigerators/ Freezers	Temperature monitoring Temperature adjustment Defrosting/cleaning	Daily As required As required
Vacuum Pumps/ Air Compressor	Drained Belts checked Lubricated	As required Monthly Annually
pH/Specific Ion Meter	Calibration/check slope Clean electrode	Daily As required
BOD Incubator	Temperature monitoring Coil and incubator cleaning	Daily As required
Centrifuge	Check brushes and bearings	Every 6 months or as needed
Water Baths	Temperature monitoring Water replaced	Daily Monthly or as needed

Table 23-5B Microbiology Analytical Equipment Maintenance		
Instrument	**Procedure**	**Frequency**
Balances	Class "1" traceable weight check Clean pan Field service	Daily, when used Daily Annually
Conductivity Meter	0.01 M KCl calibration	Daily, when used
Turbidimeter	Check light bulb	Daily, when used

Table 23-5B Microbiology Analytical Equipment Maintenance		
Instrument	**Procedure**	**Frequency**
De-ionized water polisher	Check conductivity Monitor for metals Test for bacteriological suitability Test for bacterial contamination Test for residual chlorine	Daily, Annually Annually Monthly Monthly Monthly
Autoclaves	Replace door seals Field service Monitor temperature Check with spores	As needed Annually, or as needed Each cycle Monthly
Refrigerator	Clean shelves Temperature monitoring Temperature adjustment	As needed Daily As needed
Vacuum Pumps	Lubricated	As needed, if not oil-less
pH meter	Clean/fill electrode Calibration Replace electrode	As needed Daily, when used Annually
Incubators	Temperature monitoring Temperature adjustment Clean shelves	Twice daily As needed As needed
Water Baths	Temperature monitoring Temperature adjustment Water drained and replaced Filters cleaned	Twice daily As needed Weekly Weekly
Quantitray Sealer	Sealer leak check with dye Belts/rollers cleaned Service/replacement	Monthly As needed As needed
UV Lamp	Bulbs cleaned with ethanol Output checked against original	Monthly Quarterly

23.3.2 Instrument Calibration

Generally, procedures and criteria regarding instrument calibrations are provided in the respective method SOPs.

[Instrument calibration documentation for Microbiology may be found in logbooks located in the instrument area (balance, pH meter, thermometers) and follow Standard Methods and IDPH Title 77, Public Health, Chapter 1, Subchapter d, Part 465: Certifications and Operation of Environmental Laboratories provisions.]

Initial instrument calibration and continuing instrument calibration verification are an important part of ensuring data of known and documented quality. If more stringent calibration requirements are included in a mandated method or by regulation, those calibration requirements override any requirements outlined here.

Section 24

MEASUREMENT TRACEABILITY
(TNI V1:M2 – Section 5.6)

Measurement quality assurance comes in part from traceability of standards to certified materials.

All equipment used affecting the quality of test results are calibrated prior to being put into service and on a continuing basis (see Section 23 – "Calibration Requirements"). These calibrations are traceable to national standards of measurement where available.

If traceability of measurements to SI (Systeme International or International System) units is not possible or not relevant, evidence for correlation of results through interlaboratory comparisons, proficiency testing, or independent analysis is provided.

24.1 Reference Standards

Reference standards are standards of the highest quality available at a given location, from which measurements are derived.

Reference Standards, such as ASTM Class 1 weights, are used for calibration only and for no other purpose unless it is shown that their performance as reference standards will not be invalidated.

Reference standards, such as ASTM Class 1 weights, are calibrated by an entity that can provide traceability to national or international standards. The following reference standards are sent out to be calibrated to a national standard as indicated in Section 23 – "Calibration Requirements"

- Class 1 weights, and
- NIST traceable reference thermometers.

24.2 Reference Materials

Reference materials are substances that have concentrations that are sufficiently well established to use for calibration or as a frame of reference.

Reference materials, where commercially available, are traceable to national standards of measurement, or to Certified Reference Materials, usually by a Certificate of Analysis.

Purchased reference materials require a Certificate of Analysis where available. If a reference material cannot be purchased with a Certificate of Analysis, it is verified by analysis and comparison to a certified reference material and/or demonstration of capability for characterization.

Internal reference materials, such as working standards or intermediate stock solutions, are checked as far as is technically and economically practical. In practice, working standards or intermediate stock solutions are checked against a second source at first time of use. When a second source is not available, a vendor certified different lot is accepted as a second source. In most cases, the analysis of an Initial Calibration Verification (ICV) standard or a Laboratory Control Sample (LCS) can be used as a second source confirmation. Working standards and intermediate stock solutions are given expiration dates when they are prepared based on method or regulatory requirements. These standards are used up or disposed of by the expiration date.

Additional working standards such as working class weights or internal thermometers are checked using the frequency summarized in Table 23-3 in Section 23 – "Calibration Requirements".

24.3 Transport and Storage of Reference Standards and Materials

The laboratory handles and transports reference standards and materials in a manner that protects the integrity of the materials. Reference standard and material integrity is protected by separation from incompatible materials and/or minimizing exposure to degrading environments or materials.

Reference standards and materials are stored according to manufacturer's recommendations, method SOP requirements and separately from samples.

24.4 Labeling of Reference Standards, Reagents, and Reference Materials

The laboratory has procedures for purchase, receipt and storage of standards, reagents and reference materials. Purchasing procedures are described in Section 9 – "Purchasing Services and Supplies".

Expiration dates can be extended if the reference standard or material's integrity is verified. The extended date may not be beyond the expiration date of the referenced standards used to re-verify.

24.4.1 Stock Standards, Reagents, Reference Materials and Media

Records for all standards, reagents, reference materials, and media include:

- the manufacturer/vendor name (or traceability to purchased stocks or neat compounds)
- the manufacturer's Certificate of Analysis or purity (if supplied)
- the date of receipt

If the original container does not have an expiration date provided by the manufacturer or vendor it is not required to be labeled with an expiration date. If an expiration date is provided, it must be labeled with that expiration date.

In methods where the purity of reagents is not specified, analytical reagent grade is used. If the purity is specified, that is the minimum acceptable grade. Purity is verified and documented according to Section 9 – "Purchasing Services and Supplies".

24.4.2 Prepared Standards, Reagents, Reference Materials and Media

Standards, reagents, reference materials and media are automatically assigned a unique Standard Number by the Element DataSystem® when they are entered into the LIMs. The standards are further assigned by department. The Standard Pattern used is as follows: YMDDNNN in which Y is a single digit indicating year, month is designed by a letter from "A" to "L", DD indicates the date, and NNN are sequential numbers assigned by the LIMS. For example, 2E29031 represents Standard #31, entered into LIMS on May 29, 2012.

Records for standards, reagents, reference materials, and media preparation include:

- traceability to purchased stock or neat compounds
- reference to the method of preparation
- date of preparation
- an expiration date after which the material shall not be used (unless its reliability is verified by the laboratory)
- preparer's initials (if prepared)

All containers of prepared standards, reagents, or materials are labeled with a unique ID and an expiration date.

Prepared reagents are verified to meet the requirements of the test method through routine blank analysis.

Section 25

COLLECTION OF SAMPLES
(TNI V1:M2 – Section 5.7)

PDC Laboratories, Inc. provides sampling services to a significant portion of their clients. The laboratory's responsibility in the sample collection process when the laboratory does not collect the samples lies in supplying the outside sampler with the necessary coolers, reagent water (if requested), sample containers, preservatives, sample labels, custody seals, COC forms, ice, and packing materials required to properly preserve, pack, and ship samples to the laboratory.

Sampling procedures are described in generic or site-specific sampling plans.

25.1 Sampling Containers

The laboratory offers clean sampling containers for use by clients. Select containers are purchased certified clean from a commercial vendor. These containers are ready for use and require no additional monitoring prior to use. Containers that are purchased "clean" but not certified as well as bottles that are washed at PDC must be verified clean prior to shipment to clients. The verification process is detailed in the current revision of SOP-Gen-BotQC, Bottle QC.

25.1.1 Preparing Container Orders

Containers (containing any required preservatives) are provided to the client upon request.

SOP #900_LOG-SampKitPrep, Sample Kit Request and Preparation details the procedures used for requesting sample kits, general and special packing, cooler sealing, and shipping to the client's sampling site.

25.1.2 Sampling Containers, Preservation Requirements, Holding Times

Sampling container, preservation and holding time requirements can be found in Table 25-1 as well as in the method SOPs.

If preservation or holding time requirements are not met, the procedures in Section 12 – "Control of Nonconforming Environmental Testing Work" are followed.

Table 25-1 Summary of Sampling Container, Preservation and Holding Time Requirements				
Parameter Group	**Approved Method**	**Container (Per Sample)**	**Dechlorinate / Preservation**	**Holding Time**
Drinking Water - Inorganic				
Odor	SM 2150B, 18Ed	500mL Glass	Cool, 0.1-6°C	Immediately
Alkalinity	SM 2320B, 18Ed	1 L Plastic	Cool, 0.1-6°C	14 Days
Corrosivity (Langlier Index)	SM 2330B, 18Ed	**Note A**	**Note A**	**Note A**
Hardness	SM 2340C, 18Ed	500mL Plastic	HNO3 to pH <2	6 Months
Conductivity	SM 2510B, 18Ed	500mL Plastic	Cool, 0.1-6°C	28 Days
Total Dissolved Solids (TDS)	SM 2540C, 18Ed	1 L Plastic	Cool, 0.1-6°C	7 Days
Fluoride	SM 4500F-C, 18Ed	125mL or 1 L Plastic	Cool, 0.1-6°C	28 Days
Hydrogen ion (pH)	SM 4500H-B, 18Ed	100mL Plastic	Cool, 0.1-6°C	Immediately
Nitrate	SM 4500NO3-F, 18Ed	500mL Plastic	**Notes B, C**	**Notes B, C**
Nitrite	SM 4500NO3-F, 18Ed	500mL Plastic	**Notes B, C**	**Notes B, C**
Orthophosphate	SM 4500P-E, 18Ed	16 oz Plastic or Glass	Cool, 0.1-6°C	48 Hours
Total Organic Carbon (TOC)	SM 5310D, 18Ed	40mL Amber Glass	H_2SO_4 to pH <2, Cool 0.1 - 6°C	28 Days
Foaming Agent	SM 5540C, 18Ed	1 L Glass or Plastic	H_2SO_4 to pH <2, Cool 0.1 - 6°C	7 Days
UV254	SM5910B, 19Ed	250mL Glass	Cool, 0.1-6°C	48 Hours
Hydrogen Ion (pH)	USEPA 150.1	100mL Plastic	Cool, 0.1-6°C	Immediately
Turbidity	USEPA 180.1	500mL Plastic	Cool, 0.1-6°C	48 Hours
Metals	USEPA 200.7 R4.4	250mL Plastic	HNO3 to pH <2	6 Months
Metals	USEPA 200.8 R5.4	16 or 32 oz Plastic	HNO3 to pH <2	6 Months
Mercury	USEPA 245.1 R3.0	250mL or 1 L Plastic	HNO3 to pH <2	28 Days
Anions	USEPA 300.0 R2.1	500mL Plastic	Cool, 0.1-6°C	**Note D**
Cyanide	USEPA 335.4 R1.0	16 oz Amber Plastic	NaOH to pH >12, Cool 0.1 - 6°C	14 Days
Drinking Water - Organic				
Dioxin (2,3,7,8 TCDD)	USEPA 1613RB	1 L Amber Glass	$Na_2S_2O_3$/0.1 - 6°C	365 Days
EDB & DBCP	USEPA 504.1 R1.1	40mL VOA Vial	$Na_2S_2O_3$/ZHS/0.1 - 6°C	14 Days
Hexachlorocyclopentadiene	USEPA 505 R2.1	40mL VOA Vial	$Na_2S_2O_3$/ZHS/0.1 - 6°C	14 Days
Chlorinated Pesticides	USEPA 508 R3.1	1 L Amber Glass	$Na_2S_2O_3$/0.1 - 6°C	14 Days
Chlorinated Acid Herbicides	USEPA 515.3 R1.0	250mL Amber Glass	$Na_2S_2O_3$/0.1 - 6°C	14 Days
Volatile Organics	USEPA 524.2 R4.1	40mL VOA Vial	HCL to pH <2/0.1 - 6°C	14 Days
SPE Extractable Organics	USEPA 525.2 R2.0	1 L Amber Glass	$Na_2S_2O_3$/0.1 - 6°C	14 Days
Carbamates	USEPA 531.1 R3.1	60mL Amber Glass	$Na_2S_2O_3$/MCAA to pH <3/0.1 - 6°C	28 Days
Glyphosate	USEPA 547	60mL Amber Glass	$Na_2S_2O_3$/0.1 - 6°C	14 Days
Endothall	USEPA 548.1 R1.0	1 L Amber Glass	$Na_2S_2O_3$/0.1 - 6°C	7 Days
Diquat	USEPA 549.2 R1.0	500mL HDPE	$Na_2S_2O_3$/0.1 - 6°C	7 Days
Haloacetic Acids (HAAs)	USEPA 552.2 R1.0	250mL Amber Glass	NH_4Cl	14 Days
Wastewater - Inorganic				
Color	SM 2120B, 18Ed	16 oz Plastic	Cool, 0.1-6°C	48 Hours
Acidity	SM 2310B, 18Ed	32 oz Plastic	Cool, 0.1-6°C	14 Days
Alkalinity	SM 2320B, 18Ed	1 L Plastic	Cool, 0.1-6°C	14 Days
Hardness	SM 2340C, 18Ed	500mL Plastic	HNO3 to pH <2	6 Months
Specific Conductance	SM 2510B, 18Ed	500mL Plastic	Cool, 0.1-6°C	28 Days
Residue (Total)	SM 2540B, 18Ed	1 L Plastic	Cool, 0.1-6°C	7 Days

Table 25-1 Summary of Sampling Container, Preservation and Holding Time Requirements

Parameter Group	Approved Method	Container (Per Sample)	Dechlorinate / Preservation	Holding Time
Residue (TDS)	SM 2540C, 18Ed	1 L Plastic	Cool, 0.1-6°C	7 Days
Residue (TSS)	SM 2540D, 18Ed	1 L Plastic	Cool, 0.1-6°C	7 Days
Residue (Settable Solids)	SM 2540F, 18Ed	1 L Plastic	Cool, 0.1-6°C	48 Hours
Chromium VI	SM 3500Cr-D; 18Ed	16 oz Plastic	Cool, 0.1-6°C	24 Hours
Chlorine	SM 4500Cl-G, 18Ed	16 oz Plastic	Cool, 0.1-6°C	Immediately
Cyanide-amenable to chlorination	SM 4500CN-CG, 18Ed	16 oz Amber Plastic	NaOH to pH >12, Cool 0.1 - 6°C	14 Days
Fluoride	SM 4500F-C, 18Ed	125mL or 1 L Plastic	Cool, 0.1-6°C	28 Days
Hydrogen Ion (pH)	SM 4500H-B, 18Ed	100mL Plastic	Cool, 0.1-6°C	Immediately
Total Kjeldahl Nitrogen	SM 4500NH3-H, 18Ed	500mL Plastic	H_2SO_4 to pH <2, Cool 0.1 - 6°C	28 Days
Nitrate-Nitrite (sum)	SM 4500NO3-F, 18Ed	500mL Plastic	**Note B**	**Note B**
Orthophosphate (as P)	SM 4500P-E, 18Ed	16 oz Plastic or Glass	Cool, 0.1-6°C	48 Hours
Sulfite	SM 4500SO3B, 18Ed	500mL Plastic	Cool, 0.1-6°C	Immediately
Sulfate	SM 4500SO4D, 18Ed	500mL Plastic	Cool, 0.1-6°C	28 Days
Biochemical Oxygen Demand (BOD)	SM 5210B, 18Ed	32 oz Plastic	Cool, 0.1-6°C	48 Hours
Carbonaceous BOD (cBOD)	SM 5210B, 18Ed	32 oz Plastic	Cool, 0.1-6°C	48 Hours
Chemical Oxygen Demand (COD)	SM 5220D, 18Ed	16 oz Plastic	H_2SO_4 to pH <2, Cool 0.1 - 6°C	28 Days
Total Organic Carbon (TOC)	SM 5310D, 18Ed	40mL Amber Glass	H_2SO_4 to pH <2, Cool 0.1 - 6°C	28 Days
Surfactants	SM 5540C, 18Ed	1 L Glass or Plastic	H_2SO_4 to pH <2, Cool 0.1 - 6°C	7 Days
Oil and Grease	USEPA 1664 RA	1 L Glass	H_2SO_4 or HCL to pH <2, Cool 0.1 - 6°C	28 Days
Turbidity	USEPA 180.1 R2.0	500mL Plastic	Cool, 0.1-6°C	48 Hours
Metals	USEPA 200.7 R4.4	250mL Plastic	HNO3 to pH <2	6 Months
Metals	USEPA 200.8 R5.4	16 or 32 oz Plastic	HNO3 to pH <2	6 Months
Mercury	USEPA 245.1 R3.0	250mL or 1 L Plastic	HNO3 to pH <2	28 Days
Anions	USEPA 300.0 R2.1	500mL Plastic	Cool, 0.1-6°C	**Note D**
Cyanide	USEPA 335.4 R1.0	16 oz Amber Plastic	NaOH to pH >12, Cool 0.1 - 6°C	14 Days
Ammonia	USEPA 350.1 R2.0	16 oz Plastic	H_2SO_4 to pH <2, Cool 0.1 - 6°C	28 Days
Total Kjeldahl Nitrogen	USEPA 351.1	500mL Plastic	H_2SO_4 to pH <2, Cool 0.1 - 6°C	28 Days
Nitrate (total)	USEPA 353.2 R2.0	500mL Plastic	**Note C**	**Note C**
Nitrate-Nitrite (sum)	USEPA 353.2 R2.0	500mL Plastic	**Note B**	**Note B**
Phenolics	USEPA 420.4 R1.0	500mL Amber Glass	H_2SO_4 to pH <2, Cool 0.1 - 6°C	28 Days
Wastewater - Organic				
Pesticides/PCBs	USEPA 608	1 L Amber Glass	Cool, 0.1-6°C	7 Days
Polynuclear Aromatic Hydrocarbons	USEPA 610	1 L Amber Glass	Cool, 0.1-6°C	7 Days
Volatile Organics	USEPA 624	40mL VOA Vials	$Na_2S_2O_3$/ZHS/HCL to pH <2, Cool 0.1 - 6°C	14 Days
Semi-volatile Organic Compounds	USEPA 625	1 L Amber Glass	Cool, 0.1-6°C	7 Days
Hazardous and Solid Waste - Inorganic				
Ignitability	SW-846 1020A	16 oz Glass	Cool, 0.1-6°C	28 Days
Ignitability of Solids	SW-846 1030	Plastic or Glass	Cool, 0.1-6°C	28 Days
EP Tox	SW-846 1310a	Not specified	Not specified	Not Specified
TCLP (Organic and Inorganic)	SW-846 1311	1 L Glass min.	Cool, 0.1-6°C	14 Days

Table 25-1 Summary of Sampling Container, Preservation and Holding Time Requirements				
Parameter Group	**Approved Method**	**Container (Per Sample)**	**Dechlorinate / Preservation**	**Holding Time**
SPLP (Organic and Inorganic)	SW-846 1312	1 L Glass min.	Cool, 0.1-6°C	14 Days
MEP (Organic and Inorganic)	SW-846 1320	Not specified	Not specified	Not Specified
Metals	SW-846 6010B	250mL Plastic	HNO3 to pH <2	6 Months
Metals	SW-846 6020	16 or 32 oz Plastic	HNO3 to pH <2	6 Months
Chromium VI	SW-846 7196A	16 oz Plastic	Cool, 0.1-6°C	30 Days
Mercury	Sw-846 6010B	16 or 32 oz Plastic	HNO3 to pH <2	28 Days
Mercury	SW-846 7470A	16 or 32 oz Plastic	HNO3 to pH <2	28 Days
Mercury	SW-846 7471A	Plastic or Glass	Cool, 0.1-6°C	28 Days
Cyanide	SW-846 9012A	16 oz Amber Plastic	NaOH to pH >12, Cool 0.1 - 6°C	14 Days
TOX (Total Organic Halides)	SW-846 9020B	250mL Amber Glass	H_2SO_4 to pH <2, Cool 0.1 - 6°C	28 Days
EOX (Extractable Organic Halides)	SW-846 9023	8 oz Glass	Cool, 0.1-6°C	28 Days
Hydrogen Ion (pH)	SW-846 9040B	100mL Plastic	Cool, 0.1-6°C	Immediately
Hydrogen Ion (pH)	SW-846 9045C	100mL Plastic	Cool, 0.1-6°C	Immediately
Anions	SW-846 9056	500mL Plastic	Cool, 0.1-6°C	**Note D**
Total Organic Carbon (TOC)	SW-846 9060	40mL Amber Glass	H_2SO_4 to pH <2, Cool 0.1 - 6°C	28 Days
Phenolics	SW-846 9065	500mL Amber Glass	H_2SO_4 to pH <2, Cool 0.1 - 6°C	28 Days
Phenolics	SW-846 9066	500mL Amber Glass	H_2SO_4 to pH <2, Cool 0.1 - 6°C	28 Days
Oil & Grease Extractable	SW-846 9071A	8 oz jar	Cool, 0.1-6°C	Not Specified
Paint Filter	SW-846 9095A	1 L Plastic	Cool, 0.1-6°C	6 Months
Reactive Cyanide	SW-846 Chap7/9012A	16 oz Amber Plastic	NaOH to pH >12, Cool 0.1 - 6°C	14 Days
Hazardous and Solid Waste – Organic				
Alcohols	SW-846 8015B	1 L Amber Glass; 2, 4, 9, or 16 oz Jar	Cool, 0.1 - 6°C	7 Days; 14 Days
Glycols	SW-846 8015B	1 L Amber Glass; 2, 4, 9, or 16 oz Jar	Cool, 0.1 - 6°C	7 Days; 14 Days
Diesel Range Organics (DRO)	SW-846 8015B	1 L Amber Glass; 2, 4, 9, or 16 oz Jar	Cool, 0.1 - 6°C	7 Days; 14 Days
Chlorinated Pesticides	SW-846 8081A	1 L Amber Glass; 2, 4, or 16 oz Jar	Cool, 0.1 - 6°C	7 Days; 14 Days
PCBs	SW-846 8082	1 L Amber Glass; 2, 4, or 16 oz Jar	Cool, 0.1 - 6°C	7 Days; 14 Days
Organo Phosphorus Pesticides	SW-846 8141A	1 L Amber Glass; 2, 4, or 16 oz Jar	Cool, 0.1 - 6°C	7 Days; 14 Days
Herbicides	SW-846 8151A	1 L Amber Glass; 2, 4, or 16 oz Jar	Cool, 0.1 - 6°C	7 Days; 14 Days
Volatile Organics	SW-846 8260B	40mL VOA Vials	$Na_2S_2O_3$/ZHS/HCL to pH <2, Cool 0.1 - 6°C	14 Days
Volatile Organics	SW-846 8260B	Encore samplers	1 vial – methanol; 2 vials in sodium bisulfate; Cool, 0.1 - 6°C	14 Days
Volatile Organics	SW-846 8260B	TerraCore Samplers	1 vial – methanol; 2 vials no preservative; Cool, 0.1 - 6°C	14 Days
Volatile Organics	SW-846 8260B	4 oz Jars	Cool, 0.1 - 6°C	14 Days
Volatile Organics	SW-846 8260B	4 oz Jars	Cool, 0.1 - 6°C	14 Days
Semi-volatile Organic Compounds	SW-846 8270C	1 L Amber Glass; 2, 4, or 16 oz Jar	Cool, 0.1 - 6°C	7 Days; 14 Days
Dioxins and Furans	SW-846 8290A	1 L Amber Glass	Cool, 0.1 - 6°C	30 Days
Polynuclear Aromatic Hydrocarbons	SW-846 8310	1 L Amber Glass; 2, 4, or 16 oz Jar	Cool, 0.1 - 6°C	7 Days; 14 Days

Table 25-1 Summary of Sampling Container, Preservation and Holding Time Requirements				
Parameter Group	**Approved Method**	**Container (Per Sample)**	**Dechlorinate / Preservation**	**Holding Time**
Formaldehyde	SW-846 8315A	1 L Amber Glass; 2, 4, 9, or 16 oz Jar	Cool, 0.1 - 6°C	3 Days; 3 Days
Acrylamide	SW-846 8316	1 L Amber Glass; 16 oz Jar	Cool, 0.1 - 6°C	7 Days; 14 Days
Nitroaromatics	SW-846 8330	1 L Amber Glass; 16 oz Jar	Cool, 0.1 - 6°C	7 Days; 14 Days

Abbreviations:
HCL= Hydrochloric Acid
HNO_3= Nitric Acid
$Na_2S_2O_3$ = Sodium Thiosulfate
ZHS = Zero Head Space
H_2SO_4= Sulfuric Acid
NaOH= Sodium Hydroxide
$C_6H_8O_6$ = Ascorbic Acid
MeOH = Methanol
NH_4Cl = Ammonium Chloride
HDPE = High Density Polyethylene

Note A – Calculation based on pH, TDS, Ca^{+2}, and Alkalinity. Refer to individual parameters for container, preservation, and holding time

Note B – Preservation: Cool, 0.1-6°C, H_2SO_4 to pH<2 for Nitrate/Nitrite; Holding time: Nitrate/Nitrite 28 Days

Note C – Preservation: Cool, 0.1-6°C for Nitrate only or Nitrite only; Holding time for Nitrate only or for Nitrite only is 48 Hours

Note D – Holding time: For F, Cl, Br, SO_4 is 28 Days; 14 Days for NO_3 from chlorinated supplies; 48 Hours for NO_3 (unchlorinated), NO_2 and PO_4

25.2 Sampling Plan

The laboratory uses sampling plans provided by clients or derived from the laboratory's generic plan and customized for the specific sampling site. The plan must include any factors that must be controlled to ensure the validity of the test. Sampling plans and written sampling procedures are used for sampling substances, materials or products for testing. The plan and procedures are made available at the office of the supervisor of the field sampling crew. Active landfill sites will have sampling plans on-site; however, closed facilities do not maintain documents on site.

The laboratory's procedures for dealing with nonconformances are used when the client requests any deviations from the sampling plan or sampling procedures. The requests are documented and included in the final test report.

25.3 Sampling Records

The following relevant sampling data are recorded on field data forms: sampling procedure used, the date and time of sampling, the identification of the sampler, environmental conditions (if relevant), the sampling location, field measurements taken, well integrity checklist, containers collected and other comments relevant to the sampling location.

Field sampling records are scanned and stored as electronic files.

Section 26

HANDLING SAMPLES AND TEST ITEMS
(TNI V1:M2 – Section 5.8 and Section 1.7 of Technical Modules TNI V1:M 3-7)

26.1 Sample Receipt

When samples are received at the laboratory, the Chain of Custody (COC) is reviewed, the condition is documented, the samples are given unique identifiers, and they are logged into the sample tracking system – the Element DataSystem® LIMS.

26.1.1 Chain of Custody

The Chains of Custody or sample submission sheets from the field samplers are reviewed. This documentation is completed in the field and provides a written record of the handling of the samples from the time of collection until they are received at the laboratory. Section 25 – "Collection of Samples" outlines what information is needed on this record. The Chain of Custody form also provides information on what type of testing is being requested and can act as an order for laboratory services in the absence of a formal contract. An example Chain of Custody form can be found in Figure 26-1. Chain of Custody and any additional records received at the time of sample submission are maintained by the laboratory. A graphic image of a COC that has been scanned and saved as a .jpg, .bmp or .pdf file format is stored in the Element DataSystem®. Work Order Reports and any other paperwork received at sample receipt are forwarded to the appropriate project manager.

26.1.1.1 Legal Chain of Custody

The laboratory has procedures for legal Chain of Custody services as specified in SOP # 900_LOG-Custody, Evidentiary Custody Procedures. If samples are noted as being used for legal/evidentiary purposes, special Chain of Custody procedures are put into place by the laboratory. Custody seals are sent by the lab if the sampling containers are ordered from the laboratory, shipping records are maintained with the Chain of Custody, internal Chain of Custody is initiated that provides additional documentation of internal handling by analysts and a disposal record is provided.

26.2 Sample Acceptance

Procedures for opening shipping containers and examining samples are provided in SOP # 900_LOG-Login, Sample Receipt and Login.

The laboratory has a sample acceptance policy that is made available to clients. The policy is provided in Figure 26-2 and may be found on the back of the Chain of Custody. It emphasizes the need of providing proper documentation (to include

sample ID, location, date and time of collection, collector's name, preservation type, sample type and any special remarks about the sample), labeling of sample containers to include a unique sample ID, use of appropriate containers, adherence to holding times, and sample volume requirements. In addition the laboratory has nonconformance/corrective action procedures to handle samples that don't meet the requirements above or show signs of damage, contamination or inadequate preservation. Data will be appropriately qualified where samples are reported that do not meet sample acceptance requirements.

The laboratory checks samples for the conditions above, where appropriate, to evaluate sample acceptance. Criteria regarding preservation, holding time and sample volume requirements can be found in Section 25 – "Collection of Samples" Table 25-1. Any discrepancies, missing information, bottle damage, insufficient sample volume, etc. will be noted and the appropriate project manager notified. The project manager will contact the client to obtain this information. The project manager will document this contact and the direction given - 1) the sample is rejected as agreed with the client, 2) the decision to proceed is documented and agreed upon with the client, 3) the condition is noted on the Chain of Custody form and/or lab receipt documents, and 4) the data are qualified in the report.

26.2.1 Preservation Checks

The following preservation checks are performed and documented:

26.2.1.1 *Thermal preservation:*

a. For temperature preservation, the temperature must be within the range of 0.1 -6°C for those samples that require preservation at 4°C.

b. Samples that are delivered to the lab the same day as they are collected are likely not to have reached a fully chilled temperature. This is acceptable if the samples were received on ice and the chilling process has begun.

c. Record on the receipt form if ice is present and the temperature.

Chlorine checks:

d. Samples from potable water supplies are checked for residual chlorine upon initiation of sample preparation as required by method or by client request.

pH checks:

e. The pH of samples requiring acid/base preservation is checked upon initiation of analysis.

26.3 Sample Identification

Samples, including subsamples, extracts and digestates, are uniquely identified in a permanent chronological record to prevent mix-up and to document receipt of all sample containers.

Samples are assigned sequential numbers based on the Work Order coding pattern (YMMNNNN). The work order number references more detailed information kept in the Element DataSystem®. For example, in sample number 2070420-01A, the "2" indicates 2012 (sequence of numbers repeats each decade), "07" indicates month, "0420" represents the next sequential number and "01" represents the sample number. A letter is assigned to the sample number which reflects the specific sample container used. The sample containers are "lettered" as part of the login process.

The following information is included in the Work Order:

- Client and project name
- Project Number
- Date and time of receipt at lab
- Name of person who received the samples
- Unique laboratory identification number
- Name of person making the entries
- Client Project Manager
- Lab Project Manager
- Due date
- Comments

In addition, the following information is maintained and linked to the log-in record:

- Date and time of sampling linked to the date and time of laboratory receipt.
- Unique field identification number linked to the laboratory sample ID.
- Analyses requested (including applicable approved method numbers) linked to the laboratory sample ID.
- Comments regarding rejection (if any).

Documentation received regarding the sample, such as Chain-of-Custodies, is retained electronically after being scanned into the Element DataSystem®. Login summary reports are generated the evening of each work day by the LIMS. The summary report is stored on the X: drive and is used as a reference to previously logged samples and for auditing purposes.

26.4 Sample Aliquots / Subsampling

In order for analysis results to be representative of the sample collected in the field, the laboratory has subsampling procedures as revealed in SOP # 900_QA-CompRedSubsmp, Compositing, Size Reduction and Subsampling.

26.5 Sample Storage

Storage conditions are monitored for any required criteria, verified, and the verification recorded in logbooks.

Samples that require thermal preservation are stored under refrigeration that is +/-2°C of the specified preservation temperature unless regulatory or method specific criteria require something different. For samples with a specified storage temperature of 4°C, storage at 0.1 to 6°C is acceptable.

Samples are held secure, as required. Samples are accessible only to laboratory personnel.

Samples are stored apart from standards, reagents, food or potentially contaminating sources, and such that cross-contamination is minimized. All portions of samples, including extracts, digestates, leachates, or any product of the sample are maintained according to the required conditions.

26.6 Sample Disposal

Samples are retained a minimum of 7 to 14 days after the report is sent out unless other arrangements have been made between the client and the laboratory.

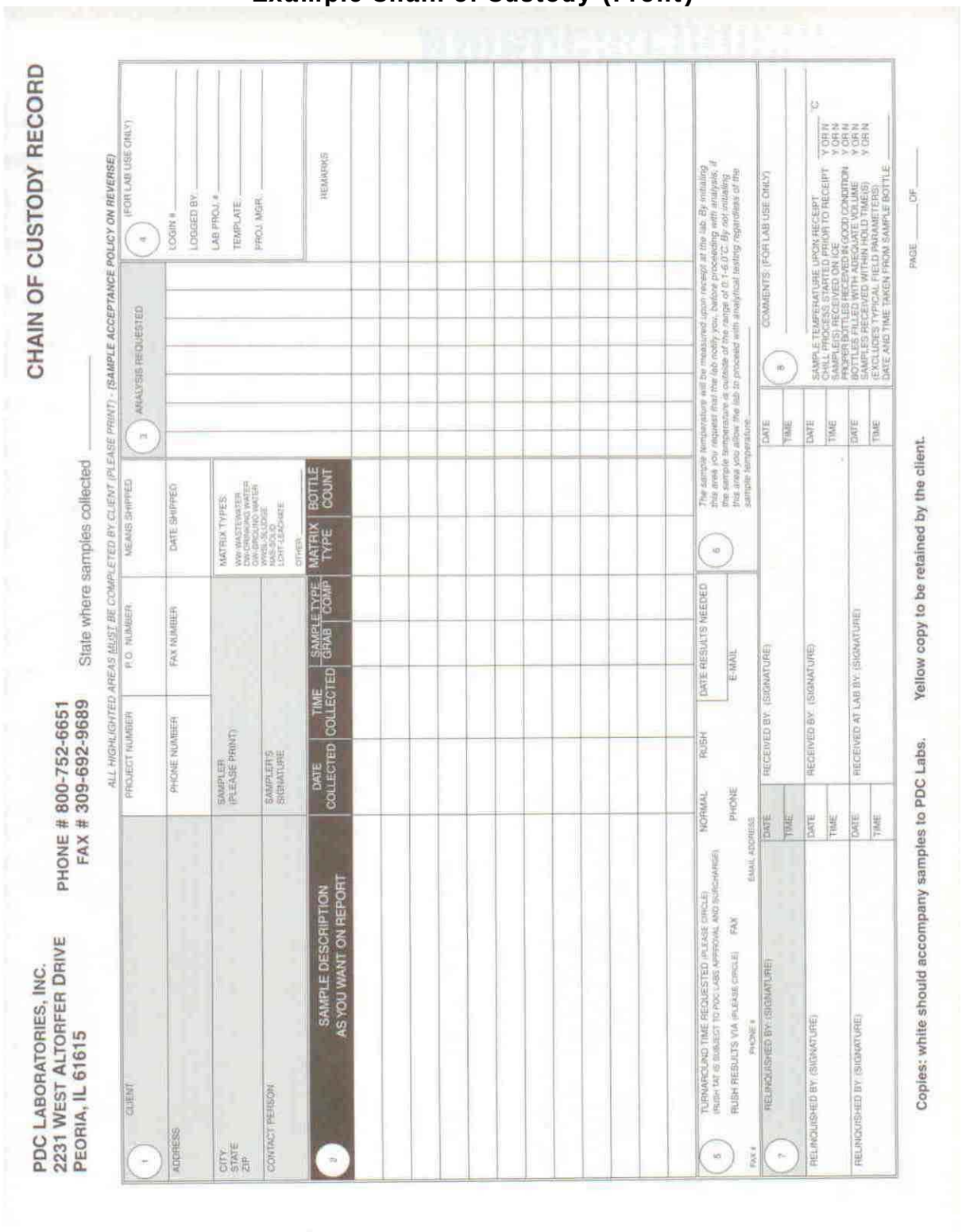
Samples are disposed of according to Federal, State and local regulations. Procedures are described in SOP # 900_QA-Sample Disposal, Sample Disposal for the disposal of samples, digestates, leachates, and extracts.

26.7 Sample Transport

Samples that are transported under the responsibility of the laboratory, where necessary, are done so safely and according to storage conditions. This includes moving bottles within the laboratory. Specific safety procedures are addressed outside of this document.

Sample shipping procedures are described in SOP # 900_LOG-SampKitPrep, Sample Kit Request and Preparation.

Figure 26-1
Example Chain of Custody (Front)



CHAIN OF CUSTODY RECORD

PDC LABORATORIES, INC.
2231 WEST ALTORFER DRIVE
PEORIA, IL 61615

PHONE # 800-752-6651
FAX # 309-692-9689

State where samples collected _____

ALL HIGHLIGHTED AREAS MUST BE COMPLETED BY CLIENT (PLEASE PRINT) - (SAMPLE ACCEPTANCE POLICY ON REVERSE)

1 CLIENT | PROJECT NUMBER | P.O. NUMBER | MEANS SHIPPED | 3 ANALYSIS REQUESTED | 4 (FOR LAB USE ONLY)

ADDRESS | PHONE NUMBER | FAX NUMBER | DATE SHIPPED

CITY, STATE ZIP | SAMPLER (PLEASE PRINT) | MATRIX TYPES: WW-WASTEWATER DW-DRINKING WATER GW-GROUND WATER WWSL-SLUDGE MAS-SOLID LIQW-LEACHATE OTHER

CONTACT PERSON | SAMPLER'S SIGNATURE

LOGIN # _____
LOGGED BY: _____
LAB PROJ. # _____
TEMPLATE: _____
PROJ. MGR.: _____

2 SAMPLE DESCRIPTION AS YOU WANT ON REPORT	DATE COLLECTED	TIME COLLECTED	SAMPLE TYPE: GRAB	SAMPLE TYPE: COMP	MATRIX TYPE	BOTTLE COUNT	REMARKS

5 TURNAROUND TIME REQUESTED (PLEASE CIRCLE) NORMAL RUSH
(RUSH TAT IS SUBJECT TO PDC LABS APPROVAL AND SURCHARGE)
RUSH RESULTS VIA (PLEASE CIRCLE) FAX PHONE E-MAIL
FAX # PHONE # EMAIL ADDRESS

DATE RESULTS NEEDED _____

6 *The sample temperature will be measured upon receipt at the lab. By initialing this area you request that the lab notify you before proceeding with analysis, if the sample temperature is outside of the range of 0.1-6.0°C. By not initialing this area you allow the lab to proceed with analytical testing regardless of the sample temperature.* _____

7 RELINQUISHED BY: (SIGNATURE) | DATE | TIME | RECEIVED BY: (SIGNATURE) | DATE | TIME

RELINQUISHED BY: (SIGNATURE) | DATE | TIME | RECEIVED BY: (SIGNATURE) | DATE | TIME

RELINQUISHED BY: (SIGNATURE) | DATE | TIME | RECEIVED AT LAB BY: (SIGNATURE) | DATE | TIME

8 COMMENTS: (FOR LAB USE ONLY)

SAMPLE TEMPERATURE UPON RECEIPT _____ °C
DATE PROCESS STARTED PRIOR TO RECEIPT Y OR N
SAMPLE(S) RECEIVED ON ICE Y OR N
PROPER BOTTLES RECEIVED IN GOOD CONDITION Y OR N
BOTTLES FILLED WITH ADEQUATE VOLUME Y OR N
SAMPLES RECEIVED WITHIN HOLD TIME(S) Y OR N
(EXCLUDES TYPICAL FIELD PARAMETERS)
DATE AND TIME TAKEN FROM SAMPLE BOTTLE _____

PAGE _____ OF _____

Copies: white should accompany samples to PDC Labs. Yellow copy to be retained by the client.

Figure 26-2
Example Chain of Custody – Sample Acceptance Policy (Back)

(1) CLIENT NAME: Client's Company name.
ADDRESS: Client's mailing address.
CITY, STATE, ZIP: Client's City, State and Zip Code for mailing.
CONTACT PERSON: Person to receive results.
PROJECT #/NUMBER: Client's reference to the project or work involved with these samples.
P.O. NUMBER: Client's invoicing information.
MEANS OF SHIPPED: UPS, Federal Express, Postal Service, courier, hand carried, etc.
PHONE #/NUMBER: Client's phone number (please include area code)
FAX #/NUMBER: Client's fax number (please include area code)
DATE SHIPPED: Month, date, and year samples were shipped or delivered to the lab.
SAMPLER: Name of sample collector.
SAMPLER'S SIGNATURE: Signature of sample collector
STATE WHERE SAMPLES COLLECTED: Enter the state if different from client address.

(2) SAMPLE # DESCRIPTION: The unique sample description you want to appear on the analytical report.
DATE COLLECTED: Date sample was collected. For composite samples, this is typically the date when the last aliquot was added.
TIME COLLECTED: Time sample was collected. For composite samples, this is typically the time when the last aliquot was added.
SAMPLE TYPE: Place an "X" in the box marked "GRAB" if the sample was collected at one time from one specific location. Place an "X" in the box marked "COMP" if the sample is a composite of samples collected at one or more times or locations, and combined to make one sample.
MATRIX TYPE: From the key above this field. If "OTHER", please identify.
BOTTLE COUNT: Total number of containers submitted for the sample.

(3) ANALYSIS REQUESTED: Write the analysis name (or an abbreviation), the name of a group of tests, or the method number you would like us to perform. Examples are Suspended Solids, SS, TCLP Metals, 503 Sludge Reqts, Method 8080, etc. Place an "X" in the small boxes that correspond to the sample(s) on which you want these tests performed.
REMARKS: List special instructions about the sample here. This space can also be used for listing additional analysis, or to request an extra copy of the report to be sent to an alternate person/address.

(4) To be completed by laboratory personnel.

(5) TURNAROUND TIME REQUESTED: Circle "NORMAL" if you want routine 10 working day TAT. If faster results are needed, circle "RUSH" and, if possible, call the lab in advance to schedule this work. Surcharges apply for non-routine.
RUSH RESULTS VIA: Choose method by which you would like to receive the RUSH results by circling either "FAX" "PHONE" or "E-Mail." List the appropriate number if different from that listed in section 1.

(6) Place your initials on the line if you would like the lab to call you, before proceeding with analysis, if the temperature of your sample(s) is outside the 0.1-6.0°C range. Many of the analytical methods, compliance regulations, and lab accreditation rules require that the samples be kept within this range until analyzed. There are ways to help ensure that the samples remain cold during shipping. Contact your project manager for further information.

(7) RELINQUISHED BY / RECEIVED BY: This form must be signed each time the sample(s) changes hands. Chain-of-Custody seals are available upon request, if needed.

(8) To be completed by laboratory personnel.

Sample Acceptance Policy for Chain of Custody -

Under the National Environmental Laboratory Accreditation Program (NELAP) and other state programs, PDC Laboratories **MUST** follow specific required procedures when accepting samples. *Your* records of sample collection, handling, and transport are an important part of *our* ability to *efficiently and effectively* meet these laboratory accreditation requirements.

Samples not meeting the accreditation requirements for proper containers, preservation, receipt temperature and documentation/labeling may not be accepted until the proper information is received and discrepancies resolved.

CONTACT YOUR PROJECT MANAGER IF YOU REQUIRE ASSISTANCE.

Samples accepted based upon receiving a completed chain of custody form and purchase order or other documentation authorizing work is or has been provided. Note: Receipt of a Chain of Custody only with samples is considered proper authorization for PDC Laboratories Inc. to analyze samples and obligates client to pay for such services. Work is performed under PDC Laboratories' Standard Terms, Conditions and Operating Procedures unless superceded by specific contract documents.

1. It is recommended to use the sample bottles supplied by PDC Labs. This ensures that the proper bottle types and preservatives are used and adequate volume for analysis is provided. Sample containers should be filled to the neck of the container, with the exception of vials for VOC/VOA/THM and bottles for TOX analysis, which should be filled completely leaving zero headspace. Bottles should not be rinsed with sample, as this will remove any preservative in preserved bottles. The only exception to this if the sample reacts with the preservative in the VOC/VOA/THM vial. As the collection of sample is your responsibility, it is recommended that you have and adhere to a Sampling Plan.
2. Many of the test methods, as well as EPA compliance programs, require samples are kept cool during the shipping process. Failure to do so may cause your results to be unacceptable to any applicable regulatory authorities. In an attempt to keep the sample temperature near 4°C, coolers should contain ice bags. Frozen freezer packs are less effective. It is recommended to pre-cool the samples in an ice bath prior to shipment. This makes the cooling in shipping more effective. The temperature of the samples will be measured upon receipt at the lab. If the temperature is not within the range of 0.1- 6°C, and the client has requested notification, login procedures are stopped until direction is provided from the client. The project manager will contact the client to obtain this information. The project manager will document this contact and the information provided. Any required information not supplied by the client will be indicated in the final report package. Contact your project manager for additional information regarding how to attain this temperature range.
3. Samples should be shipped to the lab as soon as possible. This helps to meet the maximum allowable holding times that are part of each analytical method. If the allowable holding time is exceeded when samples arrive at the lab, login procedures are stopped until direction is provided from the client. The project manager will contact the client to obtain this information. The project manager must document this client contact, and the direction the client gives on the COC, or include other similar documentation in the report package.
4. Chain of Custody (COC) forms must accompany the samples. The purpose of the COC is to identify the sample. Samples must be labeled such that the samples/sample containers can be linked to the COC form. The following information must be included on the COC: client name and address, sample collector's name, purchase order number, sample description/location, date and time of collection, sample type, matrix, total number of containers, and the requested analysis. Any discrepancies, missing information, bottle damage, insufficient sample volume, etc. will be noted and the appropriate project manager notified. The project manager will contact the client to obtain missing information or resolve discrepancies. The project manager will document this client contact, and the direction given by the client. Any information not ultimately supplied by the client will be noted in the final report package.

Thank you for using PDC Laboratories, Inc.
Please call 800-752-6651 if you have any questions about completing this form.

Section 27

QUALITY ASSURANCE FOR ENVIRONMENTAL TESTING*(TNI V1:M1, V1:M2 – Section 5.9 and Section 1.7 of Technical Modules TNI V1:M 3-7)*

PDC Laboratories, Inc. has procedures for monitoring the validity of the testing it performs. The qualities of test results are recorded in such a way that trends are detectable, and where practicable, are statistically evaluated. To evaluate the quality of test results, the laboratory utilizes: certified reference materials or cultures and/or internal quality control using secondary reference materials, control charting, proficiency testing samples, replicate or confirmation analyses, comparison to historical data, retesting of retained samples and correlation of results for different characteristics of a sample.

In addition to procedures for calibration, the laboratory monitors quality control measurements such as blanks, blank spikes (BS), matrix spikes (MS), duplicates, surrogates and internal standards to assess precision and accuracy. Proficiency Testing samples are also analyzed to assess laboratory performance.

Quality control data are analyzed and, when found to be outside pre-defined criteria, action is taken to correct the problem and to prevent incorrect results from being reported. Data associated with quality control data outside of criteria and still deemed reportable will be qualified so the end user of the data may make a determination of the usability of the data - see Section 28 – "Reporting of Results".

Note: The Microbiology Section is certified by the Illinois Department of Public Health and as such does not fall under the 2009 TNI Standard. However, the Microbiological Section quality control elements are included for reference in this document.

27.1 Essential Quality Control Procedures

The quality control procedures specified in test methods are followed by laboratory personnel. The most stringent of control procedures is used in cases where multiple controls are offered. If it is not clear which is the most stringent, that mandated by test method or regulation is followed.

For test methods that do not provide acceptance criteria for an essential quality control element such as blank spike recovery or where no regulatory criteria exist, acceptance criteria are developed. Acceptance criteria are established from data within the laboratory. Using a minimum of results from 20-30 analysis, the laboratory develops control limits from the mean percent recovery ($\overline{X}$) and standard deviation (S) of the percent recovery. These data are used to establish upper and lower control limits as follows:

$$\text{UPPER CONTROL LIMIT} = \overline{X} + 3\sigma_{n-1}$$
$$\text{LOWER CONTROL LIMIT} = \overline{X} - 3\sigma_{n-1}$$

Note: A minimum control limit of 10% will be used for all surrogate, blank spike, and matrix spike lower control limits.

In some specialized projects, the client may set the criteria recovery for the various quality control elements. These limits are modified by the respective department manager in the Element DataSystem® on an "as-needed" basis.

Written procedures to monitor routine quality controls including acceptance criteria are located in the test method SOPs, except where noted, and include such procedures as:

- use of blank spike samples and blanks to serve as positive and negative controls for chemistry methods;
- use of blank spike samples to monitor test variability of laboratory results;
- use of calibrations, continuing calibrations, certified reference materials and/or PT samples to monitor accuracy of the test method;
- measures to monitor test method capability, such as limit of detection, limit of quantitation, and/or range of test applicability, such as linearity;
- use of regression analysis, internal/external standards, or statistical analysis to reduce raw data to final results;
- use of reagents and standards of appropriate quality and use of second source materials as appropriate;
- procedures to ensure the selectivity of the test method for its intended use;
- measures to assure constant and consistent test conditions, such as temperature, humidity, rotation speed, etc., when required by test method;
- use of sterility checks for equipment, media and dilution water for microbiology; and
- use of positive and negative culture controls for microbiology.

27.2 Internal Quality Control Practices

Analytical data generated with QC samples that fall within all prescribed acceptance limits indicate the test method is deemed to be in control.

QC samples that fall outside QC limits indicate the test method are deemed to be out of control (nonconforming) and that corrective action is required and/or that the data are qualified (see Section 12 – "Control of Nonconforming Environmental Testing Work" and Section 14 - "Corrective Actions").

Detailed QC procedures and QC limits are included in test method standard operating procedures (SOPs). QC limits are also stored in the Element DataSystem® used during the evaluation of data entered into the LIMS.

All QC measures are assessed and evaluated on an on-going basis, so that trends are detected.

27.2.1 General Controls

The following general controls are used:

27.2.1.1 Positive and Negative Controls such as:

a. Blanks (negative)
b. Blank Spikes (positive)
c. Sterility checks and control cultures (positive and negative).

27.2.1.2 Selectivity is assured through:

a. absolute and relative retention times in chromatographic analyses;
b. two-column confirmation when using non-specific detectors;
c. use of acceptance criteria for mass-spectral tuning (found in test method SOPs);
d. use of the correct method according to its scope assessed during method validation; and
e. for microbiology only, use of reference cultures (positive and negative) from a recognized manufacturer (where applicable).

27.2.1.3 Consistency, Variability, Repeatability, and Accuracy are assured through:

a. proper installation and operation of instruments according to manufacturer's recommendations or according to the processes used during method validation;
b. monitoring and controlling environmental conditions (temperature, access, proximity to potential contaminants);
c. selection and use of reagents and standards of appropriate quality; and
d. cleaning glassware appropriate to the level required by the analysis as demonstrated with method blanks.

   Note: SOP #301_WC-GLASSCLEANING, Glassware Cleaning Procedure and SOP #300_GLASS, Organic Department Glassware Cleaning describe the procedures for general glassware cleaning.

e. For microbiology, glassware care includes use of borosilicate glassware, use of detergents designed for laboratory use, testing for alkaline or acid residue with bromothymol blue, and conduct of the Inhibitory Residue test when the detergent is changed, the dishwashing procedure is changed, a new lot of detergent is used or annually, whichever is more frequent.
f. following SOPs and documenting any deviation, assessing for impact, and treating data appropriately;

g. testing to define the variability and/or repeatability of the laboratory results, such as replicates;

h. use of measures to assure the accuracy of the test method, including calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures; and

i. use of duplicate plate counts on positive samples (microbiology only).

27.2.1.4 Test Method Capability (also see Section 22 – "Environmental Methods and Method Validation") is assured through:

a. establishment of the limit of detection where appropriate;

b. establishment of the limit of quantitation or reporting level; and/or

c. establishment of the range of applicability such as linearity.

27.2.1.5 Data reduction is assured to be accurate by:

a. selection of appropriate formulae to reduce raw data to final results such as regression;

b. following specific procedures for data reduction such as manual integration procedures;

c. periodic review of data reduction processes to assure applicability; and

d. microbiological calculations, data reduction, and statistical interpretations specified by each test method.

27.2.1.6 Sample Specific controls are used to evaluate the effect of sample matrix on the performance of the selected analytical method (not a measure of laboratory performance):

Examples:

- Matrix Spike and Matrix Spike Duplicate (MS/MSD)
- Surrogate Spikes
- Sample Duplicates

27.2.1.7 The following tables summarize the key elements of a quality control system for a laboratory performing chemistry and microbiology testing.

Table 27-1 Essential Quality Control Elements for Chemistry

Item	Frequency	Acceptance Criteria	Corrective action
Negative Control (Method Blank)	1/batch	Method specific or reporting limit	Qualify data and take corrective action
Positive Control (Blank Spike)	1/batch	Method specific or determined by lab	Reprocess, reanalyze, or qualify data.

Table 27-1 Essential Quality Control Elements for Chemistry			
Item	**Frequency**	**Acceptance Criteria**	**Corrective action**
Matrix Spike; Matrix Spike Duplicates *Note : Samples are designed as data quality indicators for a specific sample using the designated method. These controls alone are not used to judge a laboratory's performance.*	Per method requirement	Method specific or determined by laboratory	Corrective action and qualify data.
Surrogate spikes *See note above.*	Per method requirement	Method specific or determined by laboratory	Corrective action and qualify data
Matrix Duplicates *See note above.*	Per method requirement	Method specific or determined by laboratory	Corrective action and qualify data
Continuing Calibration Verification	Per method requirement	Method specific or determined by the laboratory	Reanalyze standard immediately; Corrective action
Initial calibration Verification	Start of each analytical run	Method specific or determined by laboratory	Reanalyze standard immediately; Corrective action

Table 27-2 Essential Quality Control Requirements for Microbiology – All Methods			
Item	**Frequency**	**Acceptance Criteria**	**Corrective Action[2]**
Sterility check containers	One container (bottle) for each lot or batch sterilized (NSGM)	No growth	Investigate cause If necessary reject the lot Notify supplier
Sterility check dilution water	One per batch of dilution water (NSGM)	No growth	Investigate cause If necessary reject the batch
Positive control[1]	Pure culture of target organisms/ each lot and batch of medium (prior to first use of medium)	Positive reaction	Investigate cause If necessary reject the medium
Negative control[1]	Pure culture of non-target organisms/each lot and batch of medium (prior to first use of medium)	Negative reaction	Investigate cause If necessary reject the medium

Table 27-2 Essential Quality Control Requirements for Microbiology – All Methods			
Item	**Frequency**	**Acceptance Criteria**	**Corrective Action[2]**
Duplicate colony counts (For numeric results only)	Quarterly on one positive sample for each month performed.	Same analyst <5% difference between counts Two analysts <10% difference between counts	Investigate cause Qualify data
1) Microorganisms may be single use preparations or cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism. 2) Corrective Action may include the need to retrain. 3) NSGM: Non-selective growth media			

Table 27-3 Essential Quality Control Requirements for Microbiology – Filtration Methods Only			
Item	**Frequency**	**Acceptance Criteria**	**Corrective Action**
Sterility check	Each lot of media prior to first use. Also done on containers, reagents and materials prior to first use. Use NSGM for containers, reagents and materials.	No growth	Investigate cause If necessary reject unacceptable lots
Method blank	Beginning/end of each run Select one: - 1 for every 10 samples - UV sterilize after each sample filtration Done as part of the test, use method media.	No growth	Investigate cause Reject data if beginning blank is contaminated
Filter lot comparison	Five filters for each new lot of membrane filters are compared to five filters from the old lot (NSGM)	T-statistic from student's T-test less than 2.78	Investigate cause If necessary reject the lot
Target organism verification (D.3.4.b)	Method specific	Confirmation of reaction	Investigate cause

Table 27-4 Essential Quality Control Requirements for Microbiology – Pour Plate Methods Only			
Item	**Frequency**	**Acceptance Criteria**	**Corrective action**
Method Blank	Minimum of one plate per batch Done as part of test, use method media	Internally defined 0 cfu/plate	Investigate cause, qualify/ reject data

Table 27-5 Stock Cultures		
Item	**Frequency**	**Handling**
Reference cultures	Single use	Preserved and handled per mfg. specifications
Reference culture Reference stock	Culture stocks to make working stocks	Preserved and not refrozen Handling per mfg specs
Working stocks	Not transferred more than five times. Not sub-cultured to replace reference stocks	

27.2.2 Specific Controls

27.2.2.1 Method Blanks

Method blanks are processed along with and under the same conditions as the associated samples to include all steps in the method. A method blank must be analyzed at a minimum of one per preparation batch. When no separate preparation method is used the batch is defined as the environmental samples that are analyzed with the same method and personnel, using the same lots of reagents, not to exceed the analysis of twenty environmental samples, not including method blanks, blank spikes, matrix spikes and matrix duplicates. The matrix of the method blank must be similar to the associated samples and be free from any analytes of interest. Method blanks are not required for some analyses such as pH, conductivity, flashpoint, etc.

Contaminated blanks are identified according to the acceptance limits in the test method SOPs or laboratory documentation.

The laboratory identifies a blank as contaminated when analyte results are greater than the reporting limit AND greater than 1/10 of that found in any sample, or where the contamination affects the sample results according to test method requirements or client objectives.

When a blank is determined to be contaminated, the cause must be investigated and measures taken to minimize or eliminate the problem.

Data that are unaffected by the blank contamination (non-detects or other analytes) are reported unqualified.

Sample data that are suspect due to the presence of a contaminated blank are reanalyzed, qualified, or voided.

27.2.2.2 Blank Spikes

Blank Spikes (BS) are prepared from analyte free water or other clean matrix, and spiked with verified and known amounts of analytes for the purpose of establishing precision or bias measurements.

Blank Spikes are analyzed at a frequency mandated by method, regulation, or client request, whichever is more stringent. The standard frequency of BS preparation and analysis is one per analytical batch or as otherwise stated in a laboratory SOP. Exceptions would be for those analytes where no spiking solution is available, such as TSS, TDS, Total Volatile Solids, Total Solids, pH, color, odor, or turbidity**.** When no separate preparation method is used the batch is defined as the environmental samples that are analyzed with the same method and personnel, using the same lots of reagents, not to exceed the analysis of twenty environmental samples, not including method blanks, blank spikes, matrix spikes and matrix duplicates.

The analytes to be spiked in the BS are specified in the test method SOP. In some cases a client may specify a list of analytes for spiking and the request is handled using the laboratory's nonconformance procedures.

The results of laboratory control samples (BS) are calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria. The laboratory documents the calculation in the test method SOP and as follows:

$$\%R = \frac{AV}{TV} \times 100$$

Where
AV = Analyzed Value
TV = True Value

The individual BS is compared to the acceptance criteria as published in the mandated test method, or where there are no established criteria, the laboratory established limits as described above.

27.2.2.3 Matrix Spikes and Matrix Spike Duplicates

Matrix Spikes and Matrix Spike Duplicates (MS/MSD) are environmental samples fortified with a known amount of analyte to help assess the effect of the matrix on method performance.

The laboratory procedure for MS/MSD includes spiking appropriate analytes at appropriate concentrations, calculating percent recoveries and relative percent difference (RPD), and evaluating and reporting the results. The procedure can be found in the test method SOP and as follows:

$$\%R = \frac{AV}{TV} \times 100$$

Where

AV = Spike Result – Sample Result
TV = True Value

$$RPD = \frac{|S - D|}{\frac{(S + D)}{2}} \times 100$$

Where:

S=Sample Concentration
D=Duplicate Concentration

Where there are no established criteria, acceptance criteria are established from data within the laboratory based on blank spike recoveries. Using a minimum of results from 20-30 analyses, the laboratory develops control limits from the mean percent recovery ($\overline{X}$) and standard deviation (S) of the percent recovery. These data are used to establish upper and lower control limits for MS/MSD as follows:

UPPER CONTROL LIMIT = $\overline{X} + 3\sigma_{n-1}$
LOWER CONTROL LIMIT = $\overline{X} - 3\sigma_{n-1}$

For MS/MSD results outside established criteria corrective action is documented or the data are reported with appropriate data qualifying codes. Only the data from the spiked sample is qualified.

27.2.2.4 Surrogate Spikes

Surrogate spikes are substances with chemical properties and behaviors similar to the analytes of interest used to assess method performance in individual samples. Surrogates are added to all samples (in test methods where surrogate use is appropriate) prior to sample preparation or extraction.

Surrogate recovery results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory uses data generated within the laboratory. Using a minimum of results from 20-30 analyses, the laboratory develops control limits from the mean percent recovery ($\overline{X}$) and standard deviation (S) of the percent recovery. These data are used to establish upper and lower control limits for MS/MSD as follows:

UPPER CONTROL LIMIT = $\overline{X} + 3\sigma_{n-1}$
LOWER CONTROL LIMIT = $\overline{X} - 3\sigma_{n-1}$

Note: A minimum of 10% will be used for all surrogate lower control limits.

For surrogate results outside established criteria, data are evaluated to determine the impact. Corrective actions may include use of a qualifier, re-analysis, re-extraction and analysis, or discussion with the client as appropriate.

27.3 Proficiency Test Samples or Interlaboratory Comparisons

27.3.1 Compliance to Accreditation Requirements

The laboratory analyzes at least two TNI-compliant PT samples per calendar year for each accreditation Fields of Proficiency Testing (FoPT) for which the laboratory is accredited. An exception is made for analytes where there is no PT available from any PTPA approved PT provider at least twice per year. In these cases the lab will run the PTs in the minimum time frame the PTs are available and not at all if they are not available.

The successive PTs are analyzed at least five months apart and no more than 7 months apart unless the PT is being used for corrective action to maintain or reinstate accreditation, in which case the dates of successive PT samples for the same accreditation FoPT is at least fifteen days apart.

27.3.2 PT Sample Handling, Analysis and Reporting

The laboratory does not share PT samples with other laboratories, does not communicate with other laboratories regarding current PT sample results, and does not attempt to obtain the assigned value of any PT sample from the PT provider.

Proficiency Testing (PT) samples are treated as typical samples in the normal production process where possible, including the same analysts, preparation, calibration, quality control and acceptance criteria, sequence of analytical steps, number of replicates, and sample log-in. PT samples are not analyzed multiple times unless routine environmental samples are analyzed multiple times. Where PT samples present special problems in the analysis process, they will be treated as laboratory samples where clients have special requests.

The type, composition, concentration and frequency of quality control samples analyzed with the PT samples are the same as with typical samples.

Prior to the closing date of a study, laboratory personnel do not:

- Subcontract analysis of a PT sample to another laboratory being run for accreditation purposes.
- Knowingly receive and analyze a PT for another laboratory being run for accreditation purposes.
- Communicate with an individual from another laboratory concerning the analysis of the PT sample.
- Attempt to find out the assigned value of a PT from the PT Provider.

The laboratory maintains low level methods and techniques that require the use of low level PTs. These PTs are analyzed and reported in the same manners as other PTs.

The laboratory evaluates and reports analytical results as follows:

a. For instrument technology that employs a multi-point calibration, the laboratory evaluates the analytical result to the value of the lowest calibration standard established for the test method used to analyze the PT sample. The working range of the calibration under which the PT sample is analyzed is the same range as used for routine environmental samples.

   A result for any FoPT at a concentration above or equal to the lowest calibration standard is reported as the resultant value.

   A result for any FoPT at a concentration less than the lowest calibration standard is reported as less than the value of the lowest calibration standard.

b. For instrument technology (such as ICP-AES or ICP-MS) that employ standardization with a zero point and a single point calibration standard, the laboratory shall evaluate the analytical result to the limit of quantitation (LOQ) established for the test method used to analyze the PT sample. The LOQ is the same as used for routine environmental samples.

   A result for any FoPT at a concentration above or equal to the LOQ is reported as the resultant value.

   A result for any FoPT at a concentration less than the LOQ is reported as less than the value of the LOQ.

The laboratory reports the analytical results for FoPTs to the PT provider on or before the closing date of the study using the reporting format specified by the provider.

On or before the closing date of the study, the laboratory authorizes the PT provider to release the laboratory's final evaluation report directly to the laboratory's Primary accrediting body as well as any other accrediting/certifying agency.

The laboratory institutes corrective action procedures for failed PT samples following the guidelines in Section 14 – "Corrective Action".

Retention of PT records is similar to that maintained for regular environmental samples. In addition the lab maintains a copy of the online data entry summary when the PT results are submitted online.

27.4 Data Review

The laboratory reviews all data generated in the laboratory for compliance with method, laboratory and, where appropriate, client requirements.

Initially, the analyst reviews data for acceptability of quality control measures and accuracy of the final result(s). After the initial review, the analyst considers all manual transfers and calculations of data in detail and checks all electronic transfers of data.

27.4.1 Review of Manually Recorded Data

For those analyses that do not lend themselves to the electronic transfer of data, the information required for traceability of the results is recorded in paper-based logbooks. Data are recorded in the logbook promptly at the time of analysis in black ink. The analyst reviews the required QC elements and sample data at the time of analysis. Upon completion, the analyst signs and dates the logbook to indicate that they have performed the steps indicated and that the analysis meets acceptance criteria or has exceptions that are noted in the comments section. Careful attention is paid to ensure that all required columns are filled in as necessary. A reviewer checklist is completed and signed/dated. The results are manually entered into the Element DataSystem®.

The Data Entry/Review Tables (DETs) used by the Element DataSystem® employ various colors and symbols to indicate problems and status settings of data and calculated results. If the DET does not show any values or entries in a color (other than black), then there are no flagged or out-of-range values. The use of a placeholder column within the Element DataSystem® is used as a reminder that an ancillary action has been completed, such as pH verification. If no value is entered, a red-flag appears that a data response is needed. The DET may show one or more other colors that indicate various problems with the data.

For example:

- Black: Default color, indicates no problems with data
- Orange: Indicates the final result equals or exceeds one or more preset flag levels. The flag levels that are exceeded will also be colored orange.
- Red: Indicates a QC value is missing, a flag level is exceeded or required data is missing. The missing or inappropriate QC value will also be colored red.
- Purple: Indicates that a result that was in red has been qualified.

The analyst reviews the data in the Element DataSystem® and qualifies the data as appropriate. The data is released to a project manager who performs a final review to ensure that the data is coherent, that QC results are acceptable, QC

exceptions are appropriately flagged and results are in line with historical values, if known.

27.4.2 Review of Electronically Transferred Data

Electronic bench sheets have been created in the Element DataSystem® to take the place of traditional paper-based logbooks. These bench sheets guide the analyst in recording all of the information required for the traceability of the analysis. The bench sheets include space for recording quality control measurements and standards documentation for the QC elements. Data are recorded on the bench sheets promptly at the time of the preparation or analysis. Proper documentation procedures must be used. Analysts review sample data and the QC information at the time of analysis and indicate if the QC parameters met the acceptance criteria. The analyst will note on the bench sheet any exceptions that are found in the “Comments” section of the bench sheet.

During data transfer from an instrument, an electronic data file is generated by the instrument and saved in the Element DataSystem®. The data file is loaded into a program that converts the data in a format that can be read by the LIMS. During data processing, the program checks the quality control measurements for acceptability. Quality control analyses that do not meet the QC criteria are qualified by the analyst.

The Data Entry/Review Tables (DETs) used by the Element DataSystem® employ various colors and symbols to indicate problems and status settings of data and calculated results. If the DET does not show any values or entries in a color (other than black), then there are no flagged or out-of-range values. The DET may show one or more other colors that indicate various problems with the data.

For example:

- Black: Default color, indicates no problems with data
- Orange: Indicates the final result equals or exceeds one or more preset flag levels. The flag levels that are exceeded will also be colored orange.
- Red: Indicates a QC value is missing and a flag level is exceeded. The missing or inappropriate QC value will also be colored red.
- Purple: Indicates that a result that was in red has been qualified.

The analyst reviews the data in the Element DataSystem® and qualifies the data as appropriate. The data is released to a project manager who performs a final review to ensure that the data is coherent, that QC results are acceptable, QC exceptions are appropriately flagged and results are in line with historical values, if known.

Section 28

REPORTING THE RESULTS
(TNI V1:M2 – Section 5.10)

The result of each test performed is reported accurately, clearly, unambiguously, and objectively and complies with all specific instructions contained in the test method.

Laboratory results are reported in a test report that includes all the information requested by the client and necessary for the interpretation of the test results and all information required by the method used.

Data are reported without qualification if they are greater than the lowest calibration standard, lower than the highest calibration standard, and without compromised sample or method integrity. The test reports may be issued as hardcopy or by electronic data transfer provided that the requirements of the TNI Standard are met.

Note: The Microbiology Section is certified by the Illinois Department of Public Health (IDPH) and as such does not fall under the 2009 TNI Standard. The Microbiology Section maintains reports specific to the program requirements of their certifying agency.

28.1 Test Reports

The standard report format has been designed to accommodate each type of test performed and to minimize the potential for misunderstanding or misuse.

The Element DataSystem® report generating function contains a drop-down list of available reports. The most common report issued is the PDC_1.rpt. Other formats are available based on client requirements.

For routine reporting, the system is queried daily for login groups by project manager that are “reportable”. A list of reportable logins is generated and presented on the screen. A draft report is generated for each login for review. At this time any corrections to sample descriptions, dates, times, comments, etc. can be made as needed. Any questions or issues based on the draft reports are taken to the appropriate department manager to be addressed.

After reviewing a draft of all available reports, the project manager returns to the list and highlights those logins that are ready to report either “as is” or “as corrected”. The project manager then chooses the “spool” options and reviews the parameters. The spool process generates the PDC_1 report format for each highlighted login in an electronic file. The report files (in PDF format) are staged by the Element DataSystem® and either printed for mailing or emailed to the contacts and any other report recipients that are specified in client reporting options for each project.

Reports can also be individually generated and manually printed or emailed when needed. This is typically done when a client calls and needs a report immediately and the project manager is not prepared to spool all available reports.

Each test report generated contains the following information unless not required by the client requirements:

a. a title, “Laboratory Results”;

b. the name and mailing address of the laboratory, the laboratory telephone number, fax number and name of the client’s project manager or designee of the project manager;

c. unique identification of the test report, such as a workorder number, on each page and a pagination system that ensures that each page is recognized as part of the test report and a clear identification of the end of the report, such as 3 of 10;

d. the name and address of the client;

e. the identification of the method used;

f. a description and unambiguous identification of the sample(s) tested, including the client identification code;

g. the date of sample receipt when it is critical to the validity and application of the results, date and time of sample collection, dates the tests were performed, the time of analysis if the required holding time for either activity is less than or equal to 72 hours;

h. reference to the sampling plan and procedures used by the laboratory where these are relevant to the validity or application of the results is not found on the standard report but may be added under “Notes” or in a separate narrative;

i. the test results, units of measurement, an indication of when results are reported on any basis other than as received (e.g. dry weight), failures identified (Appendix F – Data Qualifiers);

j. the name, function, and signature or an equivalent electronic identification of the person authorizing the test report, and the date of issue;

k. where relevant, a statement to the effect that the results relate only to the samples;

l. Any non-accredited tests or parameters shall be clearly identified as such to the client when claims of accreditation to this Standard are made in the analytical report or in the supporting electronic or hardcopy deliverables (PDC_1 cert.rpt); and

m. a statement that the report shall not be reproduced except in full without written approval of the laboratory.

28.2 Supplemental Test Report Information

When necessary for interpretation of the results or when requested by the client, test reports may include the following additional information:

a. deviations from, additions to, or exclusions from the test method, information on specific test conditions, such as environmental conditions, and any non-standard conditions that may have affected the quality of the results, and any information on the use and definitions of data qualifiers;

b. a statement of compliance/non-compliance when requirements of the management system are not met, including identification of test results that did not meet the laboratory and regulatory sample acceptance requirements, such as holding time, preservation, etc.;

c. where applicable and when requested by the client, a statement on the estimated uncertainty of the measurement;

d. where appropriate and needed, opinions and interpretations. When opinions and interpretations are included, the basis upon which the opinions and interpretations are documented. Opinions and interpretations are clearly marked as such in the test report. Opinions may be used as needed on some microbiology reports – which do not fall under the TNI Standard. (A narrative can be used for explanation but any opinion or interpretation is limited to comparison with a regulatory limit.

e. additional information which may be required by specific methods or client;

f. qualification of results with values outside the calibration range (E qualifier) as appropriate.

In addition to the items above, for test reports that include copies of field log sheets, the following is provided when necessary for the interpretation of the results:

a. the date of sampling (on COC form and field log sheets);

b. unambiguous identification of the material sampled;

c. the locations of the sampling based on client provided monitoring point descriptions;

d. a reference to the sampling plan and procedures used when requested (sampling technique information such as bailer, bladder pump, mitertial pump, etc. is included on field log form);

e. details of any environmental conditions during sampling that may affect the interpretations of the test results (on field log sheets);

f. any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned (comments/observations on field log sheets).

28.3 Environmental Testing Obtained from Subcontractors

Test results obtained from tests performed by subcontractors are clearly identified on the test report by subcontractor name and/or accreditation number.

The subcontractors report their results in writing or electronically. A copy of the actual report received from the subcontractor on their letterhead is attached to the PDC report in its entirety.

28.4 Electronic Transmission of Results

All test results transmitted by telephone, fax, telex, e-mail, or other electronic means comply with the requirements of the TNI Standard and associated procedures to protect the confidentiality and proprietary rights of the client (see Section 22- "Environmental Methods and Method Validation").

28.4.1 Electronic Data Deliverables

Industry standard formats and client –specific custom formats for electronic data deliverables are available in the Element DataSystem® as requested by the client.

28.5 Amendments to Test Reports

Amendments to a test report after it has been issued are made only in the form of another document or data transfer. All supplemental reports meet all the requirements for the initial report and the requirements of this *Quality Manual*.

Amended test reports include the title, "Revised Laboratory Results" or the statement, "Revised Report" appended to the "Notes" section via the use of the narrative function of Element to assure they can be differentiated from other test reports. The report requirements of the client dictate which format is used.

When it is necessary to issue a complete new report, the new report is uniquely identified and contains a reference to the original that it replaces.

Appendix A

Ethics and Data Integrity Policy Overview

The mission of PDC Laboratories, Inc. is to generate and report data of known and documented quality in a fashion that meets our clients' requirements. Our policy is to use good professional practices, to maintain quality, to uphold the highest quality of service and to comply with the TNI Standard. In support of this mission, our quality assurance program has been implemented as an integral part of laboratory management and practice. The PDC Laboratories, Inc. Quality Manual (QM) describes the standard practices and requirements that have been established to assure the quality of the laboratories' services. It describes the requirements, implementation, management and review of these practices. The Laboratory Vice President, directors, department managers, section supervisors and staff members are individually obligated to comply with its stated requirements, responsibilities and objectives.

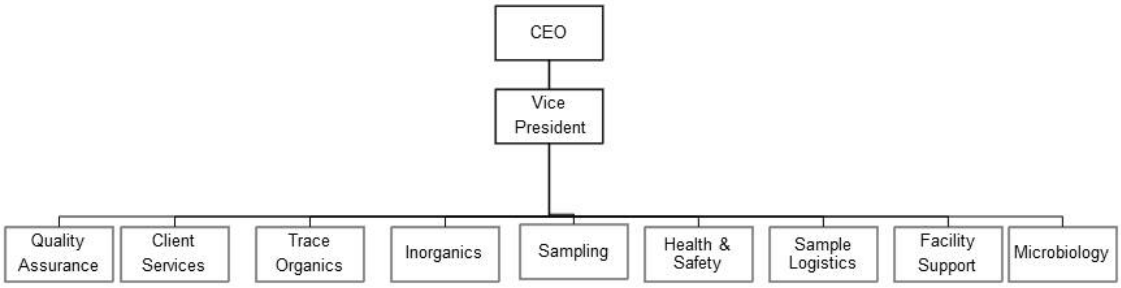
The PDC Laboratories, Inc. management is committed to comply with the TNI Standard and will continually improve the effectiveness of the management system that results from implementation of the Standard in its entirety. Each staff member must familiarize themselves with the quality documentation and to implement the quality policies and procedures in their work. Every laboratory employee must ensure that the generation and reporting of quality analytical data is a fundamental priority.

The laboratory ensures that personnel are free from any commercial, financial, and other undue pressures, which might adversely affect the quality of work. All employees are trained annually on ethical principles and procedures surrounding the data that is generated. The laboratory maintains a strict policy of client confidentiality.

Appendix B

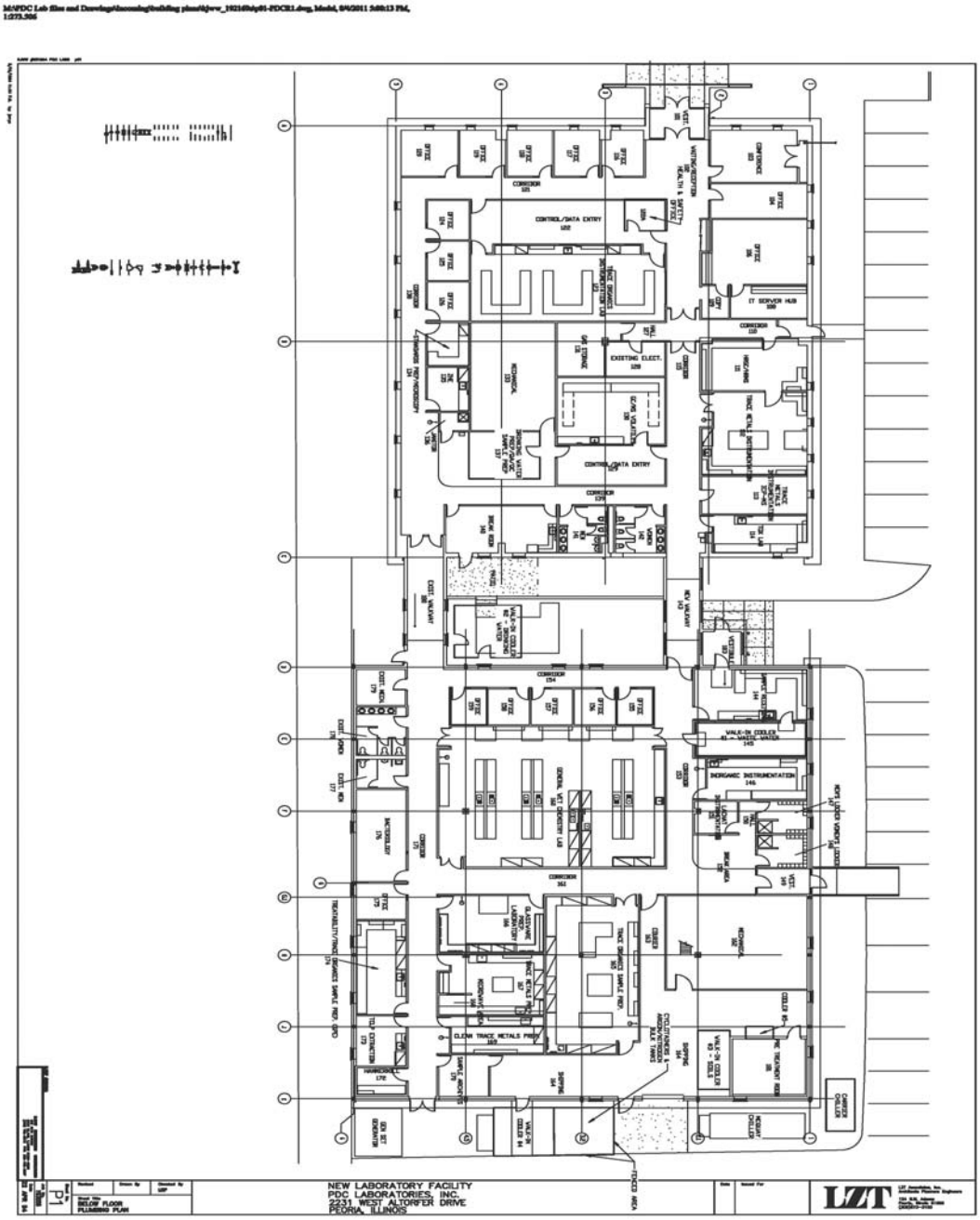
General Laboratory Organization Chart

(The most current chart can be obtained from the Quality Assurance Department.)



Appendix C

Laboratory Floor Plan



Appendix D

Terms and Definitions

Acceptance Criteria: Specified limits placed on characteristics of an item, process, or service defined in requirement documents.

Accreditation: The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

Accreditation Body (AB): The territorial, state or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation.

Accuracy: The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator.

Aliquot: A measured portion of a sample, or solution taken for sample preparation or analysis

Analysis Date: The calendar date of analysis associated with the analytical result reported for an accreditation or experimental field of proficiency testing.

Analyst: The designated individual who performs the “hands-on” analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

Analyte: The specific component measured in a chemical analysis

Analytical Uncertainty: A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis.

Assessment: The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of laboratory accreditation).

Audit: A systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management, and reporting aspects of a system to determine whether QA/QC and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives.

Batch: Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one (1) to twenty (20) environmental samples of the same quality systems matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be twenty-four (24) hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include

prepared samples originating from various quality system matrices and can exceed twenty (20) samples.

Bias: The systematic or persistent distortion of a measurement process, which causes errors in one direction (i. e., the expected sample measurement is different from the sample's true value).

Blank: A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include:

Method Blank: A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all the steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

Calibration Blank: An aliquot of the standard diluent (water or organic solvent) that is not carried through the sample preparation scheme. It is analyzed to verify that the analytical system is free from contamination. Also referred to an Instrument Blank.

Equipment Blank: A sample of analyte-free media which has been used to rinse common sampling equipment to check the effectiveness of decontamination procedures.

Field Blank: Blank that is prepared in the field by filling a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken and analyzed to determine the level of contamination introduced in to the sample due to sampling technique and environmental factors.

Trip Blank: An aliquot of laboratory pure water that accompanies the sample containers to the sampling site and returns to the laboratory. Used for volatile samples. The holding time for a trip blank begins when samples are collected. Trip blanks do not need to be analyzed if VOC, GRO and/or PVOC compounds are not detected in any of the associated water samples.

Storage Blank: An aliquot of laboratory pure water stored and analyzed with samples at the laboratory. It is a test for contamination in sample storage.

Blank Spike (BS): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes and taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a reference method. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. Also called a Laboratory Control Sample (LCS)

Blank Spike Duplicate (BSD): A replicate blank spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte. Also called a Laboratory Control Sample Duplicate (LCSD)

Blind Sample: A sample known by the submitter, that is submitted in such a way that the analyst does not know its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process.

Breakdown: A measure of the decomposition of certain analytes (DDT and Endrin) into by-products

Calibration: A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

Support equipment calibration: The values realized by standards are established through the use of reference standards that are traceable to the International System of Units (SI).

Method calibration: The values realized by standards are typically established through the use of reference materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

Calibration Curve: The mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.

Calibration Factor: A measure of the gas chromatographic response of a target analyte to the mass injected. The calibration factor is analogous to the Relative Response Factor (RRF) used in gas chromatograph/mass spectrometer (GC/MS) volatile and semivolatile fraction analyses.

Calibration Standard: A substance or reference material used for calibration.

Certified Reference Material (CRM): Reference material, accompanied by a certificate, having a value, measurement uncertainty, and stated metrological traceability chain to a national metrology institute.

Chain of Custody Form: Record that documents the possession of samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses. See also Legal Chain of Custody Protocols.

Check Standard: A standard of known value used to verify titrant strength and/or used to determine that the method is in control when a blank spike or calibration curve is not used.

Completeness: The percentage of measurements made which are judged to be valid measurements. The completeness goal is to generate sufficient amount of valid data based on project needs.

Confirmation: Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to: second column confirmation, alternate wavelength, derivatization, mass spectral interpretation, alternative detectors, or additional cleanup procedures.

Continuing Calibration Verification Standard (CCV): A standard used to verify the continued acceptability of the initial calibration curve. A continuing calibration verification standard must be repeated at the beginning and end of each analytical batch and every 10-20 samples, whichever is more frequent depending on the method requirements.

Control Chart: A graphical plot of test results with respect to time or sequence of measurements together with limits within which they are expected to lie when the system is in a state of statistical control.

Control Limit: the limits shown on a control chart beyond which it is highly improbable that a point could lie while the system remains in a state of statistical control.

Corrective Action: The action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent reoccurrence.

Data Audit: A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality (i.e., that they meet specified criteria).

Data Quality Objectives (DQO): During the planning phase of a project requiring laboratory support, the data user must establish the quality of data required from the investigation. Such statements of data quality are known as DQOs. DQOs are qualitative and quantitative statements of the data which are required to support specific decisions or regulatory actions. DQOs must take into account sampling considerations as well as analytical protocols.

Data Reduction: The process of transforming the number of data items by arithmetic or statistical calculation, standard curves, and concentration factors, and collating them into a more useful form.

Demonstration of Capability (DOC): A procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision.

Document Control: the act of ensuring that documents (and revisions there to) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed.

Field of Accreditation: Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

Field of Proficiency Testing (FoPT): Analytes for which a laboratory is required to successfully analyze a PT sample in order to obtain or maintain accreditation, collectively defined as: matrix, technology/method, analyte

Finding: An assessment conclusion referenced to a laboratory accreditation standard and supported by objective evidence that identifies a deviation from a laboratory accreditation standard requirement.

Headspace: Any area in a container not completely filled by the sample, thus allowing gases to collect in that space

Holding Time: The maximum time that can elapse between two (2) specified activities.

Initial Calibration Verification Standard (ICV): A standard used to verify the accuracy of calibration standards. Prepared from a second source than that of the calibration standards, its known value is measured against the calibration curve determining the integrity of the working standards. Also referred to as an external verification standard or a check standard.

Instrument Detection Limit (IDL): A statistically determined detection limit to estimate an instrument's sensitivity (the smallest signal that can be distinguished from background noise). The IDL is obtained by analyzing seven consecutive standards, without preparation, if possible, at a concentration of three to five times the estimated IDL. These standards must meet criteria of bias and precision.

Internal Standard: A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method.

Laboratory Control Sample (LCS): Refer to Blank Spike (BS)

Laboratory Control Sample Duplicate (LCSD): Refer to Blank Spike Duplicate (BSD)

Legal Chain of Custody Protocols: Procedures employed to record the possession of samples from the time of sampling through the retention time specified by the client or program. These procedures are performed at the special request of the client and include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples by the laboratory. In addition, these protocols document all handling of the samples within the laboratory.

Limit(s) of Detection (LOD): A laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility.

Limit(s) of Quantitation (LOQ): The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

Linear Dynamic Range (LDR): The concentration range over which the instrument response to an analyte is linear.

Matrix: The substrate of a test sample.

Matrix Duplicate: A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision. Precision results are reported as relative percent difference (RPD).

Matrix Interference: The influence of the sample matrix or sample components upon the ability to qualitatively identify or quantitatively measure compounds in environmental samples.

Matrix Spike (MS): A sample prepared, taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a referenced method, by adding a known amount of target analyte to a specified amount of sample for which an independent test result of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Matrix Spike Duplicate (MSD): A replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

Measurement System: A method, as implemented at a particular laboratory, and which includes the equipment used to perform the test and the operator(s).

Method: A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.

Method Detection Limit (MDL): The minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero, and is determined from the analysis of a sample in a given matrix containing the analyte. MDLs are determined by analyzing a minimum of seven consecutive standards that have been processed through all preparatory steps. These standards must meet criteria of bias and precision.

Method Reporting Limit (MRL): The lowest amount of an analyte in a sample that can be quantitatively determined with stated, acceptable precision and accuracy under stated analytical conditions (i.e., the lowest standard in a calibration curve).

Method of Standard Addition (MSA): A method in which small increments of a substance under measurement are added to a sample to establish a response function, and by extrapolation, to determine the amount of the substance originally present in the sample.

Modals: Words used to signify requirements in a specification, method or procedure.

May: denotes permitted action, but not required action (truly optional).

Must: denotes an absolute requirement that has to be met (required)

Shall: denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled.

Should: denotes a guideline or recommendation whenever noncompliance with the specification is permissible (recommended).

Narrative: The portion of the data package which includes laboratory, contract, case and sample number identifications, and descriptive documentation of any problems encountered in processing the samples along with corrective action taken and problem resolution.

National Environmental laboratory Accreditation Conference (NELAC): A voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP.

National Environmental laboratory Accreditation program (NELAP): The overall National Environmental Laboratory Accreditation program of which NELAC is part.

National Institute of Standards and Technology (NIST): A federal agency of the US Department of Commerce's Technology Administration that is designated as the United States National Metrology Institute (NMI).

Negative Control: measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results.

Parallax Error: Type of error that occurs when the scale of the glass measuring device is not viewed from a perpendicular position. Looking down on the meniscus causes it to appear higher that where it really is. Looking up at the meniscus causes it to appear lower than it really is.

Post Digestion Spike: The addition of a known amount of standard after digestion.

Positive Control: Measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects.

Precision: The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.

Preservation: Any conditions under which a sample must be kept in order to maintain chemical and/or biological integrity prior to analysis.

Primary Accreditation Body (Primary AB): the accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.

Procedure: A specified way to carry out an activity or process. Procedures can be documented or not.

Proficiency Testing: A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

Proficiency Testing Program (PT Program): The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.

Proficiency Testing Provider (PTP): A person or organization accredited by the TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT program.

Proficiency Testing Provider Accreditor (PTPA): An organization that is approved by TNI to accredit and monitor the performance of proficiency testing providers.

Proficiency Test Sample (PT Sample): A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria.

Proficiency Testing Study (PT Study): A single complete sequence of circulation of proficiency testing samples to all participants in a proficiency test program.

Protocol: A detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed.

Quality Assurance (QA): An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

Quality Control (QC): The overall system of technical activities that measures the attributes and performance of a process, item , or service against defined standard to verify that they meet the stated requirements established by the client; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring that the results are of acceptable quality.

Quality Control Sample (QCS): A sample used to assess the performance of all or a portion of the measurement system. One of any number of samples, such as Certified Reference materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control.

Quality Manual: A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

Quality System: A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products(items), and services. The quality system provides the framework for planning implementing, and assessing work performed by the organization and for carrying out required quality assurance (QA) and quality control (QC) activities.

Quality System Matrix: These matrix definitions are to be used for purposes of batch and quality control requirements:

Air and Emissions: Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device.

Aqueous: Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. Includes surface water, ground water effluents, and TCLP or other extracts.

Biological Tissue: Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Chemical Waste: A product or by-product of an industrial process that results in a matrix not previously defined.

Drinking Water: Any aqueous sample that has been designated a potable or potential potable water source.

Non-Aqueous Liquid: Any organic liquid with <15% Settleable solids.

Saline/Estuarine: Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

Solids: Includes solids, sediments, sludges and other matrices with >15% settleable solids

Raw Data: The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, print outs of chromatograms, instrument outputs, and handwritten records.

Reference Material: Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

Reference Standard: Standard used for the calibration of working measurement standards in a given organization or at a given location.

Retention Time: The time elapsed from sample injection on a gas or ion chromatograph until the specific compound elutes or exits from the chromatographic column on the detector. Each analyte has a characteristic retention time on a specific column allowing this information to be used to qualitatively identify the analytes in the sample.

Sample: A portion of material supplied by the client for analysis.

Sampling: Activity related to obtaining a representative sample of the object of conformity assessment according to a procedure.

Selectivity: The ability to analyze, distinguish, and determine a specific analyte or parameter from another component that may be a potential interferent or that may behave similarly to the target analyte or parameter within the measurement system.

Sensitivity: The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest.

Standard: The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of standard setting and meets the approval requirements of standard adoption organizations procedures and policies.

Standard Operating Procedures (SOPs): A written document that details the method for an operation, analysis, or action, with thoroughly prescribed techniques and steps. SOPs are officially approved as the methods for performing certain routine or repetitive tasks.

Stock Solution: A solution containing an analyte that is prepared using a reference material traceable to EPA, the National Institute of Science and Technology (NIST), or a source that will attest to the purity and authenticity of the reference material.

Surrogate Compound: A compound that behaves similarly, with respect to the analytical method, as the analytes of interest but is not normally found in environmental samples. Often surrogates are isotopic homologues of target analytes. Surrogate(s) are added to all blanks, samples and QC samples prior to preparation and analysis. Recovery of surrogates is used to assess method performance.

Technology: A specific arrangement of analytical instruments, detection systems, and/or preparation techniques.

The NELAC Institute (TNI): A non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community.

Toxic Equivalency Factor (TEF): Values assigned to each 2, 3, 7, 8-substituted dioxin and furan to approximate their toxicity in relation to 2, 3, 7, 8-TCDD.

Toxic Equivalency Quotient (TEQ): The total of each 2, 3, 7, 8-substituted dioxin and furan multiplied by the corresponding TEF. The TEQ is used to assess a sample's toxicity by expressing the results of all dioxins and furans detected as 2, 3, 7, 8-TCDD.

Traceability: The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.

Validation: The confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

Verification: Confirmation by examination and objective evidence that specified requirements have been met.

> NOTE: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.
>
> The result of verification leads to a decision either to restore in service, to perform adjustment, to repair, to downgrade, or to declare obsolete. In all cases, it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.

Working range: The difference between the Limit of Quantitation (LOQ) and the upper limit of the measurement system calibration.

ACRONYMS

A list of acronyms used in this document and their definitions are:

A

AB	–	Accrediting Body
ANSI	–	American National Standards Institute
ASQC	–	American Society for Quality Control
ASTM	–	American Society for Testing and Materials

B

BFB	-	Bromofluorobenzene
BLK	-	Blank
BOD	-	Biological Oxygen Demand
BS	-	Blank Spike
BSD	-	Blank Spike Duplicate
BTEX	-	Benzene, Toluene, Ethylbenzene, Xylenes

C

°C	–	degrees Celsius
cal	–	calibration
CAS	–	Chemical Abstract Service
CCC	-	Calibration Check Compounds
CCV	–	Continuing Calibration Verification (Standard)
CDD	-	Chlorinated Dibenzo-p-dioxin (tetra- through octa-)
CDF	-	Chlorinated Dibenzofuran (tetra- through octa-)
CERLA	-	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	-	Code of Federal Regulations
CLP	-	Contract Laboratory Program (USEPA)
COC	–	Chain of Custody
COD	-	Chemical Oxygen Demand
CRM	-	Certified Reference Material
CVAA	-	Cold Vapor Atomic Absorption
CWA	-	Clean Water Act

D

DFTPP	-	Decafluorotriphenyl phosphine
DO	-	Dissolved Oxygen
DOC	-	Demonstration of Capability
DQO	-	Data Quality Objectives
DRO	-	Diesel Range Organics

E

ECD	-	Electron Capture Detector
EDB	-	Ethylene Dibromide
EDL	-	Estimated Detection Limit
EMPC	-	Estimated Maximum Possible Concentration
EPA	-	Environmental Protection Agency

F

FID	-	Flame Ionization Detector
FoPT	-	Field of Proficiency Testing

G

GALP	-	Good Automated Laboratory Practices
GC	-	Gas Chromatograph
GC/MS	-	Gas Chromatography/Mass Spectrometry
g/L	-	grams per liter
GLP	-	Good Laboratory Practices
GRO	-	Gasoline Range Organics

H

HAZMAT	-	Hazardous Materials
HPLC	-	High Performance Liquid Chromatography
HVAC	-	Heat, Ventilation and Air Conditioning System

I

IC	-	Ion Chromatography
ICP	-	Inductively Coupled Plasma (Spectrometry)
ICP-MS	-	Inductively Coupled Plasma Mass Spectrometry
ICS	-	Interference Check Standard
ICV	-	Initial Calibration Verification (Standard)
IDC	-	Initial Demonstration of Capability
IDL	-	Instrument Detection Limit
ISO/IEC	-	Inter. Organization for Standardization/Inter. Electrochemical Commission
ISTD	-	Internal Standard

L

LCD	-	Laboratory Control Sample
LCSD	-	Laboratory Control Sample Duplicate
LDR	-	Linear Dynamic Range
LFB	-	Laboratory Fortified Blank
LIMS	-	Laboratory Information Management System
LOD	-	Limit of Detection
LUST	-	Leaking Underground Storage Tank

M

M	-	molecular ion
MB	-	Method Blank
MBAS	-	Methylene Blue Active Substances
MDL	-	Method Detection Limit
mg/kg	-	milligrams per kilogram
mg/L	-	milligrams per liter
MRL	-	Method Reporting Limit
MS	-	Matrix Spike
MSA	-	Method of Standard Additions
MSD	-	Matrix Spike Duplicate

MTBE - Methyl Tertiary Butyl Ether
m/z - mass-to-charge ratio

N

NELAC - National Environmental Laboratory Accreditation Conference
NELAP - National Environmental Laboratory Accreditation Program
NIST - National Institute of Standards and Technology
NPDES - National Pollutant Discharge Elimination System
NTU - Nephlometric Turbidity Unit

P

PAH - Polynuclear Aromatic Hydrocarbons
PCB - Polychlorinated Biphenyl
PCDD - Polychlorinated dibenzo-p-dioxins; refers to methods' full dioxin analyte list
PCDF - Polychlorinated dibenzo-p-furans; refers to methods' full furan analyte list
PFK - Perfluorokerosene
PNA - Polynuclear Aromatics
ppb - Parts per Billion
ppm - Parts per Million
ppq - Parts per Quadrillion
ppt - Parts per Trillion (ng/L; pg/g)
PT - Proficiency Test(ing)
PTP - Proficiency Testing Provider
PVOC - Petroleum Volatile Organic Compounds

Q

QA - Quality Assurance
QC - Quality Control
QCS - Quality Control Sample
QM - Quality Manual

R

RCRA - Resource Conservation and Recovery Act
RF - Response Factor
RPD - Relative Percent Difference
RRF - Relative Response Factor
RRT - Relative Response Time
RSD - Relative Standard Deviation

S

SARA - Superfund Amendments and Reauthorization Act
SDG - Sample Delivery Group
SDWA - Safe Drinking Water Act
SOC - Synthetic Organic Chemicals
SOP - Standard Operating Procedure
SPCC - System Performance Check Compounds
SPK - Spike
SPLP - Synthetic Precipitation Leaching Procedure
STD - Standard
SW-846 - Test Methods for Evaluating Solid Waste

T

TCLP	-	Toxicity Characteristic Leaching Procedure
TDS	-	Total Dissolved Solids
TEF	-	Toxic Equivalency Factor
TEQ	-	Toxic Equivalency Quotient
TNI	-	The NELAC Institute
TOC	-	Total Organic Carbon
TOX	-	Total Organic Halides
TRPH	-	Total Recoverable Petroleum Hydrocarbons
TSS	-	Total Suspended Solids
THMs	-	Trihalomethanes
TTHM	-	Total Trihalomethanes

U

ug/Kg	-	Micrograms per Kilogram
ug/L	-	Micrograms per Liter
UV/Vis	-	Ultraviolet/Visible Wavelength

V

VOC	-	Volatile Organic Compounds

W

WET	-	Whole Effluent Toxicity test
WG	-	Work Group

Z

ZHE	-	Zero Headspace Extractor

Appendix E

Laboratory Accreditation / Certification / Recognition

PDC Laboratories, Inc. maintains the following certifications and accreditations with numerous state and national entities:

Organization	Certificate Number	Matrix
Illinois Department of Public Health	17553	Microbiology
Indiana State Department of Health	C-IL-04	DW
Indiana State Department of Health	M-IL-04	Microbiology
Iowa Department of Natural Resources	240	DW; WW; SW; UST
State of Arkansas Department of Environmental Quality	12-020-0	WW; SW
State of Illinois Environmental Protection Agency	002960	DW; WW; SW
State of Kansas Department of Health and Environment	E-10338	DW; WW; SW
State of Missouri Department of Natural Resources	870	DW
State of Missouri Department of Natural Resources	870	Microbiology
State of Wisconsin Department of Natural Resources	998284430	DW; WW; SW

Legend

DW = Drinking water;
WW = Wastewater;
SW = Solid waste;
UST = Underground Storage Tanks

Copies of certificates and parameter lists for each organization are available upon request.

If accreditation is terminated or suspended, the laboratory will immediately cease to use the certificate number reference in any way and inform clients impacted by the change.

Appendix F

Data Qualifiers
(as reflected in Element DataSystem® on November 15, 2012)

Qualifier	Definition
_<0.1	<0.1
>240000	>240000
_>24200	>24200
_A	Absent
_G-	_G-
_I	Invalid
_P	Present
_S	Satisfactory
_TNTC	TNTC
_U	Unsatisfactory
>160	>160
>160000	>160000
>200	>200
>201	>201
>2420	>2420
>60000	>60000
>73	>73
>BOD	>[Custom Value]
2	Values are both under [Custom Value] mg/L and within 1 MRL of each other
A	Absent

Qualifier	Definition
A1	The presence of this analyte was confirmed using a second column but there was a disparity (> 40% RPD) between the two sets of results with no apparent chromatographic anomalies. The lower of the two results was reported.
B	Present in the method blank at [Custom Value].
B1	Blank contamination suspected and the sample result is less than MRL
B2	Contamination does not impact data since sample result is greater than ten times the contamination level.
C	The blank spike failed to meet the required acceptance criteria.
D	Result obtained through analysis of a sample dilution.
E	Concentration exceeds the instrument calibration range
F	Internal standard area failed to meet the required acceptance criteria in repeat instrumental analyses. Results should be interpreted as estimated concentrations.
Fail	Fail
G	The Method of Standard Additions [MSA] was used to quantify the concentration.
H	Test performed after the expiration of the appropriate regulatory/advisory maximum allowable hold time
HS	Headspace present
J	Estimated value; value between the MDL and MRL.
K	Filtered Only – Not Tumbled
M	Analyte failed to meet the required acceptance criteria for duplicate analysis
NA	Not Analyzed
NO	NO
NR	Not Required
O	[Custom Value]

Qualifier	Definition
P	Present
Pass	Pass
Pc	Chemical preservation discrepancy noted at the time of analysis
Pt	Thermal preservation discrepancy noted
Q1	MS Failed %R
Q2	MSD failed %R
Q3	MS/MSD both failed %R
Q4	The matrix spike recovery result is unusable since the analyte concentration in the sample is greater than four times the spike level. The associated blank spike was acceptable.
R	MS/MSD Failed %RPD
S	Surrogate compound diluted below a reliable quantitation level.
Sub	Subcontracted
T	Surrogate recovery failed to meet the required acceptance criteria in the initial analysis. Sample was re-extracted (if applicable) and re-analyzed, and the surrogate recovery was outside of the required acceptance criteria on the second analysis, also.
U	Parameter was analyzed for, but not detected above the reporting limit.
V	Verification standard recovery failed to meet the required acceptance criteria on repeat instrumental analyses.
W	Surrogate recovery failed to meet the required acceptance criteria in initial analysis. Sample was re-extracted (if applicable) beyond the maximum allowable hold time, and re-analyzed.
X	[Custom Value]
YES	YES

Appendix G

Chemistry

G.1 Method Validation

A reference method is a method issued by an organization generally recognized as competent to do so. When a laboratory is required to analyze a parameter by a specific method due to a regulatory requirement, the parameter/method combination is recognized as a reference method. Reference methods are validated by determining the LOD and/or LOQ by procedures outlined below and determining precision and bias by using the demonstration of capability procedures.

Before any non-standard or laboratory-developed methods are used in the laboratory, the laboratory determines the data quality that must be used to ensure that the data are acceptable for the intended use. Based on the intended use, the laboratory establishes quality control acceptance criteria for precision, accuracy and selectivity (if applicable). In addition, the action level (compliance level, project decision level, etc.) is used to establish the LOQ and/or LOD.

Specific procedures for the validation of laboratory-developed methods may be found in Section 22.2 of this QAM.

a. Limit of Detection (LOD)

The Limit of Detection (LOD) is the laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility.

If the laboratory does not report values below the Limit of Quantitation (LOQ) or the lowest calibration standard, if the laboratory is not required to report to the LOD, or if the method does not require a LOD study, a LOD is not required.

LODs are not required for any component for which spiking solutions or quality control samples are not available. These include, for example: residual chlorine, solids (gravimetric), BOD/cBOD, titrimetric procedures, ignitability, reactivity, and corrosivity.

The laboratory will select methods with LODs that are expected to meet the intended data use. When the method or applicable regulation specifies a LOD study, only the specified method will be used.

LODs are determined in samples that represent the quality system matrices to be evaluated. All sample processing/preparation steps and all determinative steps are used to validate the method for all targeted analytes. The representative quality system matrix will be free from the target analytes of interest or interfering analytes that impact the LOD.

When providing compliance data under 40 CFR Part 136 or equivalent delegated state program, the laboratory follows the procedures outlined in 40 CFR Part 136 Appendix B, and uses the method detection limit (MDL) derived from this procedure as the LOD. The laboratory documents the process used to derive the LOD and retains all the supporting data. Alternate means of determining the LOD may include dilution of a standard until it is no longer detected (the LOD is the level that was last detected) or establishing the LOD at a concentration that is five times the signal-to-noise ratio.

The laboratory uses the current version of the SOP, Guidelines for Performing Detection Limit (MDL) Studies to determine the LOD for a method.

Once the LOD has been determined the validity of the LOD is verified by a detection (value above zero) for each target analyte in a quality control sample of a representative quality system matrix. The concentration of the analytes in the sample will be no more than 3 times the derived LOD unless the test contains multiple analytes. In the latter case, the concentration of the target analytes will be no greater than 4 times the LOD. This verification will be performed on each instrument that is used for the test.

LODs are performed or repeated:

- before reporting the LOD for a given analyte,
- any time there is a change that affects how the method is performed, or
- when there is a change in instrumentation that affects the sensitivity of the analysis.

LODs are verified annually for each quality system matrix/technology/analyte combination, if required.

b. Limit of Quantitation

The Limit of Quantitation (LOQ) is an estimate of the minimum amount of a substance that can be reported with a specified degree of confidence.

If a LOD study is not performed, concentration values less than the LOQ are not reported but are appropriately qualified.

LOQs are not required for components or properties for which spiking solutions or QC samples are not available. These include, for example: residual chlorine, solids (gravimetric), BOD/cBOD, titrimetric procedures, ignitability, reactivity, and corrosivity.

A LOQ study includes all sample processing and analysis steps in the analytical method. The study is performed in each quality system matrix for which the test will be performed. The procedure is documented and all supporting data are retained. The resulting LOQ will be above the LOD (if determined).

The LOQ is established by the low calibration standard. Alternately, the LOQ is no less than 3 times the method detection level (MDL) or 10 times the LOD.

The laboratory will verify the LOQ by the analysis of a QC sample containing the analytes of concern at a concentration of 1 to 2 times the derived (claimed) LOQ. The LOQ is considered verified if recovery of each analyte is within the laboratory's acceptance limits, or the client's data quality objectives.

The LOQ will be verified annually for each quality system matrix, technology and analyte unless the LOD was determined or verified.

c. Precision and Bias

Precision is the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms.

Bias is the systematic error that contributes to the difference between the mean of a significant number of test results and the accepted reference value.

Precision and bias using non-reference, modified reference or laboratory-developed methods are established using the procedure outlined below and compared to the criteria established by the client (when requested), the method, or the laboratory.

Precision and bias are determined by using the demonstration of capability procedures. Samples are processed through all phases of the method (sample preparation, cleanup, analysis, etc.) and are evaluated across the analytical calibration range of the method. This study is performed for all quality system matrices for which the test is to be used.

d. Selectivity

Selectivity is the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances.

The laboratory evaluates selectivity through procedures defined in the test method SOPs. These procedures may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical or fluorescence profiles, co-precipitation evaluations, and electrode response factors.

G.2 Demonstration of Capability

Demonstration of Capability (DOC): A procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision.

Before reporting any data with a given method, a satisfactory DOC is performed. Thereafter, each analyst demonstrates continuing proficiency through the procedures outlined in Ongoing Demonstration of Capability.

In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation, and there have been no significant changes in instrument type, personnel, or method, the ongoing DOC shall be acceptable as an initial DOC. The laboratory shall have records on file to demonstrate that an initial DOC is not required.

a. Initial Demonstration of Capability (IDOC)

An IDOC is performed:

- before using any method,
- each time there is a change in instrument type, personnel or method, or
- if the laboratory or analysts has not performed the method in a twelve-month period.

The IDOC(s) for each analyst is documented in department training records. The document identifies the analyst(s) involved in preparation and/or analysis; matrix; analyte(s), class of analyte(s), or measured parameter(s); the method(s) performed; the laboratory-specific SOP used for analysis (including revision number); the date(s) of analysis; and a summary of the results used to calculate the mean recovery and standard deviations.

All raw data, preparation records, and calculations for each IDOC are retained and are available for review.

When the method specifies a procedure to be followed, only that specified procedure will be used. If the method or regulation does not specify an initial DOC procedure, the following general procedure is used:

i. The analyte (s) shall be diluted in a volume of clean quality system matrix (a sample in which no target analytes or interferences are present at concentrations that will impact the results of a specific method) sufficient to prepare four (4) aliquots at the concentration specified, or if unspecified, to a concentration of one (1) to four (4) times the limit of quantitation.

ii. At least four (4) aliquots shall be prepared and analyzed according to the method(s) either concurrently or over a period of days.

iii. Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations of the sample (in the same

units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory shall assess performance against established and documented criteria.

iv. Compare the information from (iii) above to the corresponding acceptance criteria for precision and accuracy in the method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters does not meet the acceptance criteria, the performance is unacceptable for that parameter.

v. When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst shall proceed according to a) or b) below.

a. Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with (ii) above.
b. Beginning with (ii) above, repeat the test for all parameters that failed to meet criteria.

vi. Repeated failure, however, confirms a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with (ii).

vii. When an analyte not currently found on the laboratory's list of accredited analytes is added to an existing method, an initial demonstration shall be performed for that analyte.

b. Ongoing Demonstration of Capability

After the demonstration of capability is completed, on-going proficiency is maintained and demonstrated at least annually. Each analyst is expected to consistently meet the QC requirements of the method, the laboratory SOP, client requirements and/or the TNI Standard. Ongoing DOCS are documented in department training files, and all records related to the demonstration are retained.

The on-going demonstration may be one of the following:

i. acceptable performance of a blind sample (single blind to the analyst);

Note: Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the tests.

ii. another initial DOC;

iii. at least four (4) consecutive laboratory control samples with acceptance levels of precision and accuracy. The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis. The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing LCSs for each method for each analyst each year;

iv. a documented process of analyst review using QC samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary;

v. if (i) through (iv) are not technically feasible, then analysis of real-world samples with results within a predefined acceptance criteria (as defined by the laboratory or method) shall be performed.

G.3 Calibration

Section 23.2.2 includes information on calibration of support equipment. This Section covers calibration of analytical equipment.

Initial instrument calibration and continuing instrument calibration verification are an important part of ensuring data of known and documented quality. If more stringent calibration requirements are included in a mandated method or by regulation, those calibration requirements override any requirements outlined here or in laboratory SOPs. Generally, procedures and criteria regarding instrument calibrations are provided in the individual method SOPs.

G.3.1 Initial Instrument Calibration

- Records:

  Initial instrument calibration documentation includes calculations, integrations, acceptance criteria, and associated statistics referenced in the test method SOP.

  Sufficient raw data records are collected to allow reconstruction of the initial instrument calibration. These include, at a minimum, calibration date, test method, instrument, analysis date, analyte names, analysts signature or initials, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument responses to concentration. Calibration date and expiration date (when recalibration is due) is documented for equipment requiring calibration, where practicable (see Section 23.1).

- Number of Standards and Concentrations:

  The method SOP specifies the number of calibration standards to use.

  The lowest calibration standard is the lowest concentration for which quantitative results can be reported without qualification. The lowest calibration standard is at

or below the Limit of Quantitation (LOQ) and is greater than the Limit of Detection. Results that are less than the LOQ are considered to have increased uncertainty, and are either reported with a qualifier code or explained in a case narrative.

The highest calibration standard is the highest concentration for which quantitative results can be reported. Data reported exceeding the highest calibration standard without dilutions is considered to have increased uncertainty and are reanalyzed and reported as a dilution of the sample.

- Evaluation, Verification and Corrective Action

  All initial instrument calibrations are verified with a standard obtained from a second source traceable to a national standard when commercially available. If a second source is not available, a standard prepared from a different lot may be used.

  Criteria for the acceptance of an initial instrument calibration is established (e.g., correlation coefficient or relative percent difference) and defined in the method SOP. The criteria used are appropriate to the calibration technique.

  Where appropriate, the laboratory has manual integration procedures, described in the current version of the SOP, Chromatographic Peak Integration Procedures, which are adhered to when evaluating calibration data.

  Any samples that are analyzed after an unacceptable initial calibration are re-analyzed or the data are reported with qualifiers, appropriate to the scope of the unacceptable condition (see Section 12 – "Control of Nonconforming Environmental Testing").

  Quantitation is always determined from the initial calibration unless the test method or applicable regulations require quantitation from the continuing instrument calibration verification.

  Corrective actions are performed when the initial calibration results are outside acceptance criteria. Calibration points are not dropped from the middle of the curve unless the cause is determined and documented. If the cause cannot be determined, the calibration curve is re-prepared. If the low or high calibration point is dropped from the curve, the working curve is adjusted and sample results outside the curve are qualified.

G.3.2 Continuing Instrument Calibration

- Records

  The calculations and associated statistics for continuing instrument calibration are included or referenced in the test method SOP.

  Sufficient raw data records are retained to allow reconstruction of the continuing instrument calibration verification. Continuing instrument calibration verification

records connect the continuing verification date to the initial instrument calibration.

Where appropriate, the laboratory has manual integration procedures described in the current version of the SOP, Chromatographic Peak Integration Procedures, which are adhered to when evaluating calibration data.

- Frequency

  Calibration is verified for each compound, element, or other discrete chemical species. For multi-component analytes, such as aroclors, chlordane, toxaphene, or total petroleum hydrocarbons, a representative chemically related substance or mixture is used.

  Calibration verifications are performed:

  - at the beginning and end of each analytical batch, except for instances when an internal standard is used. For methods employing internal standards, one verification is performed at the beginning of the analytical batch. Some methods have more frequent CCV requirements (see specific method SOPs). Many inorganic methods require the CCV to be analyzed after every 10 samples.
  - whenever it is expected that the analytical system may be out of calibration or might not meet verification acceptance criteria.
  - when the time period for calibration or the most recent calibration verification has expired.
  - for all analytical systems that have a calibration verification requirement. Requirements can be found in the method SOPs. Many inorganic methods require the CCV to be analyzed after every 10 samples.

- Evaluation, Verification and Corrective Actions

  The validity of the initial calibration is verified prior to sample analysis by use of continuing instrument calibration verification (CCV) standard.

  Criteria for the acceptance of a continuing calibration verification is established (e.g., correlation coefficient or relative percent difference) and defined in the test method SOP. The criteria used are appropriate to the calibration technique.

  Where appropriate, the laboratory has manual integration procedures, described in the current version of the SOP, Chromatographic Peak Integration Procedures, which are adhered to when evaluating calibration data.

  Corrective action is initiated for CCV results that are outside of acceptance criteria (see Section 12 – “Control of Nonconforming Environmental Testing”).

G.3.3 Unacceptable Continuing Instrument Calibration Verifications

If routine corrective action for continuing instrument calibration verification fails to produce second consecutive (immediate) calibration verification within acceptance criteria, then a new calibration is performed or acceptable performance is demonstrated after corrective action with two consecutive calibration verifications.

For any samples analyzed on a system with an unacceptable calibration, some results may be useable if qualified and under the following conditions:

a. If the acceptance criteria are exceeded high (high bias) and the associated samples are below detection, then those sample results that are non-detects may be reported as non-detects.
b. If the acceptance criteria are exceeded low (low bias) and there are samples that exceed the maximum regulatory limit, then those exceeding the regulatory limit may be reported.